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**Tuesday**  
**March 5, 1996**

# Federal Register

Briefings on How To Use the Federal Register  
For information on briefing in Washington, DC, see  
announcement on the inside cover of this issue.



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- FOR:** Any person who uses the Federal Register and Code of Federal Regulations.
- WHO:** Sponsored by the Office of the Federal Register.
- WHAT:** Free public briefings (approximately 3 hours) to present:
1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
  2. The relationship between the Federal Register and Code of Federal Regulations.
  3. The important elements of typical Federal Register documents.
  4. An introduction to the finding aids of the FR/CFR system.
- WHY:** To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

### WASHINGTON, DC

[Two Sessions]

- WHEN:** March 12, 1996 at 9:00 am and  
March 26, 1996 at 9:00 am
- WHERE:** Office of the Federal Register Conference Room, 800 North Capitol Street, NW., Washington, DC (3 blocks north of Union Station Metro)
- RESERVATIONS:** 202-523-4538



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**Electronic Bulletin Board**

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Executive Order 12990 of February 29, 1996

The President

## Adjustments of Rates of Pay and Allowances for the Uniformed Services, Amendment to Executive Order No. 12984

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 601 of Public Law 104-106, it is hereby ordered as follows:

Section 1. The rates of monthly basic pay (37 U.S.C. 203(a)), the rates of basic allowances for subsistence (37 U.S.C. 402), and the rates of basic allowances for quarters (37 U.S.C. 403(a)) for members of the uniformed services and the rate of monthly cadet or midshipman pay (37 U.S.C. 203(c)(1)) are adjusted as set forth on the schedule attached hereto and made a part hereof.

Sec. 2. The adjustments in rates of pay and allowances set forth on the attached schedule are effective on January 1, 1996.

Sec. 3. Section 4 and Schedule 8 of Executive Order No. 12984 of December 28, 1995, are superseded.



THE WHITE HOUSE,  
*February 29, 1996.*

**PAY AND ALLOWANCES OF THE UNIFORMED SERVICES**  
(Effective on January 1, 1996)

**Part I--MONTHLY BASIC PAY**

**YEARS OF SERVICE (COMPUTED UNDER 37 U.S.C. 205)**

Pay Grade	2 or less		Over 3		Over 4		Over 6		Over 8		Over 10		Over 12		Over 14		Over 16		Over 18		Over 20		Over 22		Over 24		Over 26			
COMMISSIONED OFFICERS																														
O-10**	\$7,145.70	\$7,397.10	\$7,397.10	\$7,397.10	\$7,397.10	\$7,397.10	\$7,681.20	\$7,681.20	\$8,106.60	\$8,106.60	\$8,686.50	\$8,686.50	\$9,268.20*	\$9,268.20*	\$9,845.40*	\$9,845.40*	\$10,427.10*	\$10,427.10*	\$11,008.80*	\$11,008.80*	\$11,590.50*	\$11,590.50*	\$12,172.20*	\$12,172.20*	\$12,753.90*	\$12,753.90*	\$13,335.60*	\$13,335.60*	\$13,917.30*	\$13,917.30*
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O-6	3,532.50	3,881.10	4,135.50	4,135.50	4,135.50	4,135.50	4,443.70	4,443.70	4,751.90	4,751.90	5,060.10	5,060.10	5,368.30	5,368.30	5,676.50	5,676.50	5,984.70	5,984.70	6,292.90	6,292.90	6,601.10	6,601.10	6,909.30	6,909.30	7,217.50	7,217.50	7,525.70	7,525.70	7,833.90	7,833.90
O-5	2,825.40	3,317.40	3,546.90	3,546.90	3,546.90	3,546.90	3,855.10	3,855.10	4,163.30	4,163.30	4,471.50	4,471.50	4,779.70	4,779.70	5,087.90	5,087.90	5,396.10	5,396.10	5,704.30	5,704.30	6,012.50	6,012.50	6,320.70	6,320.70	6,628.90	6,628.90	6,937.10	6,937.10	7,245.30	7,245.30
O-4	2,381.40	2,900.10	3,093.60	3,093.60	3,093.60	3,093.60	3,397.80	3,397.80	3,702.00	3,702.00	4,006.20	4,006.20	4,310.40	4,310.40	4,614.60	4,614.60	4,918.80	4,918.80	5,223.00	5,223.00	5,527.20	5,527.20	5,831.40	5,831.40	6,135.60	6,135.60	6,439.80	6,439.80	6,744.00	6,744.00
O-3***	2,213.10	2,474.40	2,645.40	2,645.40	2,645.40	2,645.40	2,926.80	2,926.80	3,208.20	3,208.20	3,489.60	3,489.60	3,771.00	3,771.00	4,052.40	4,052.40	4,333.80	4,333.80	4,615.20	4,615.20	4,896.60	4,896.60	5,178.00	5,178.00	5,459.40	5,459.40	5,740.80	5,740.80	6,022.20	6,022.20
O-2***	1,929.90	2,107.50	2,332.30	2,332.30	2,332.30	2,332.30	2,613.70	2,613.70	2,895.10	2,895.10	3,176.50	3,176.50	3,457.90	3,457.90	3,739.30	3,739.30	4,020.70	4,020.70	4,302.10	4,302.10	4,583.50	4,583.50	4,864.90	4,864.90	5,146.30	5,146.30	5,427.70	5,427.70	5,709.10	5,709.10
O-1***	1,675.50	1,743.90	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50	2,107.50

**COMMISSIONED OFFICERS WITH OVER 4 YEARS OF ACTIVE DUTY SERVICE  
AS AN ENLISTED MEMBER OR WARRANT OFFICER**

O-3E	-	-	-	-	-	\$2,926.80	\$3,066.90	\$3,176.70	\$3,348.90	\$3,514.50	\$3,686.70	\$3,858.90	\$4,031.10	\$4,203.30	\$4,375.50	\$4,547.70	\$4,719.90
O-2E	-	-	-	-	-	2,617.20	2,671.50	2,756.10	2,900.10	3,044.10	3,188.10	3,332.10	3,476.10	3,620.10	3,764.10	3,908.10	4,052.10
O-1E	-	-	-	-	-	2,107.50	2,251.80	2,334.60	2,419.20	2,503.80	2,588.40	2,672.90	2,757.50	2,842.10	2,926.70	3,011.30	3,095.90

\* Basic pay for these officers is limited to the rate of basic pay for level V of the Executive Schedule, which is \$9,016.80 per month.

\*\* While serving as Chairman or Vice Chairman of the Joint Chiefs of Staff, Chief of Staff of the Army, Chief of Naval Operations, Chief of Staff of the Air Force, Commandant of the Marine Corps, or Commandant of the Coast Guard, basic pay for this grade is calculated to be \$10,863.60, regardless of cumulative years of service computed under section 205 of title 37, United States Code. Nevertheless, actual basic pay for these officers is limited to the rate of basic pay for level V of the Executive Schedule, which is \$9,016.80 per month.

\*\*\* Does not apply to commissioned officers who have been credited with over 4 years of active duty service as an enlisted member or warrant officer.

PAY AND ALLOWANCES OF THE UNIFORMED SERVICES (PAGE 2)  
YEARS OF SERVICE (COMPUTED UNDER 37 U.S.C. 205)

Pay Grade	2 or less	Over 2	Over 3	Over 4	Over 6	Over 8	Over 10	Over 12	Over 14	Over 16	Over 18	Over 20	Over 22	Over 24	Over 26
WARRANT OFFICERS															
W-5															
W-4	\$2,254.80	\$2,419.20	\$2,419.20	\$2,474.40	\$2,586.90	\$2,700.90	\$2,814.30	\$3,011.10	\$3,150.90	\$3,261.60	\$3,348.90	\$3,456.90	\$3,572.70	\$3,684.00	\$3,851.10
W-3	2,049.30	2,223.00	2,223.00	2,251.80	2,277.90	2,444.70	2,586.90	2,671.50	2,756.10	2,838.60	2,926.80	3,041.10	3,150.90	3,261.60	3,428.60
W-2	1,794.90	1,941.90	1,941.90	1,998.30	2,107.50	2,223.00	2,307.30	2,391.90	2,474.40	2,561.40	2,645.40	2,728.50	2,838.60	2,938.60	3,105.60
W-1	1,495.20	1,714.50	1,714.50	1,857.60	1,941.90	2,025.00	2,107.50	2,194.50	2,277.90	2,362.80	2,444.70	2,532.30	2,632.30	2,732.30	2,932.30
ENLISTED MEMBERS															
E-9*															
E-8															
E-7	\$1,535.70	\$1,659.10	\$1,719.00	\$1,779.60	\$1,840.20	\$1,898.70	\$1,959.60	\$2,020.80	\$2,112.00	\$2,172.00	\$2,232.00	\$2,292.00	\$2,352.00	\$2,413.20	\$2,537.10
E-6	1,321.20	1,440.30	1,500.00	1,563.90	1,622.70	1,680.90	1,742.70	1,832.40	1,890.00	1,950.90	1,980.60	1,980.60	1,980.60	1,980.60	2,015.50
E-5	1,159.50	1,262.10	1,323.10	1,380.90	1,471.80	1,531.80	1,592.10	1,650.90	1,680.90	1,680.90	1,680.90	1,680.90	1,680.90	1,680.90	1,715.50
E-4	1,081.20	1,142.10	1,209.10	1,302.60	1,354.20	1,354.20	1,354.20	1,354.20	1,354.20	1,354.20	1,354.20	1,354.20	1,354.20	1,354.20	1,389.20
E-3	1,019.10	1,074.90	1,117.50	1,161.90	1,161.90	1,161.90	1,161.90	1,161.90	1,161.90	1,161.90	1,161.90	1,161.90	1,161.90	1,161.90	1,196.90
E-2	980.70	980.70	980.70	980.70	980.70	980.70	980.70	980.70	980.70	980.70	980.70	980.70	980.70	980.70	1,015.70
E-1**	874.80	874.80	874.80	874.80	874.80	874.80	874.80	874.80	874.80	874.80	874.80	874.80	874.80	874.80	909.10

\* While serving as Sergeant Major of the Army, Master Chief Petty Officer of the Navy or Coast Guard, Chief Master Sergeant of the Air Force, or Sergeant Major of the Marine Corps, basic pay for this grade is \$4,104.90, regardless of cumulative years of service computed under section 205 of title 37, United States Code.

\*\* Applies to personnel who have served 4 months or more on active duty.

\*\*\* Applies to personnel who have served less than 4 months on active duty.

## PAY AND ALLOWANCES OF THE UNIFORMED SERVICES (PAGE 3)

## Part II--BASIC ALLOWANCE FOR QUARTERS RATES

Pay Grade	Without dependents Full rate*	Partial rate**	With dependents
COMMISSIONED OFFICERS			
O-10	\$788.40	\$50.70	\$970.50
O-9	788.40	50.70	970.50
O-8	788.40	50.70	970.50
O-7	788.40	50.70	970.50
O-6	723.30	39.60	873.90
O-5	696.60	33.00	842.40
O-4	645.60	26.70	742.50
O-3	517.50	22.20	614.40
O-2	410.40	17.70	524.70
O-1	345.60	13.20	468.90
COMMISSIONED OFFICERS WITH OVER 4 YEARS OF ACTIVE DUTY SERVICE AS AN MEMBER OR WARRANT OFFICER			
O-3E	\$558.60	\$22.20	\$660.30
O-2E	474.90	17.70	595.80
O-1E	408.30	13.20	550.50
WARRANT OFFICERS			
W-5	\$655.80	\$25.20	\$716.70
W-4	582.60	25.20	657.00
W-3	489.60	20.70	602.10
W-2	434.70	15.90	553.80
W-1	363.90	13.80	479.10
ENLISTED MEMBERS			
E-9	\$478.50	\$18.60	\$630.60
E-8	439.20	15.30	581.40
E-7	375.00	12.00	539.70
E-6	339.60	9.90	498.90
E-5	313.20	8.70	448.50
E-4	272.40	8.10	390.00
E-3	267.30	7.80	363.00
E-2	217.20	7.20	345.60
E-1	193.50	6.90	345.60

\* Payment of the full rate of basic allowance for quarters at these rates to members of the uniformed services without dependents is authorized by section 403 of title 37, United States Code, and Part IV of Executive Order 11157, as amended.

\*\* Payment of the partial rate of basic allowance for quarters at these rates to members of the uniformed services without dependents who, under section 403(b) or (c) of title 37, United States Code, are not entitled to the full rate of basic allowance for quarters, is authorized by section 1009(c)(2) of title 37, United States Code, and Part IV of Executive Order 11157, as amended.

## Part III--BASIC ALLOWANCE FOR SUBSISTENCE

Officers (per month)		\$149.67
Enlisted Members (per day):		
	E-1 (less than 4 months of active duty)	All Other
Enlisted		
When on leave or authorized to mess separately	\$6.59	\$7.15
When rations in-kind are not available	7.43	8.06
When assigned to duty under emergency conditions where no messing facilities of the United States are available	9.86	10.67

## Part IV--RATE OF MONTHLY CADET OR MIDSHIPMAN PAY

The rate of monthly cadet or midshipman pay authorized by section 203(c)(1) of title 37, United States Code, is \$558.04.

# Rules and Regulations

Federal Register

Vol. 61, No. 44

Tuesday, March 5, 1996

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

## DEPARTMENT OF COMMERCE

### Bureau of Export Administration

#### 15 CFR Part 785

[Docket No. 960221039-6039-01]

RIN 0694-AB31

#### Exports to Iran; Imposition of Economic Sanctions

**AGENCY:** Bureau of Export Administration.

**ACTION:** Final rule.

**SUMMARY:** The Bureau of Export Administration (BXA) is amending the Export Administration Regulations (EAR) to reflect the imposition of additional economic sanctions on Iran as a result of the issuance of Executive Order 12959 on May 6, 1995. The Executive Order delegates implementation responsibility to the Department of the Treasury's Office of Foreign Assets Control (OFAC), including authority for exports and certain reexports.

**EFFECTIVE DATE:** March 5, 1996.

**FOR FURTHER INFORMATION CONTACT:** Hillary Hess, Office of Exporter Services, Bureau of Export Administration, Telephone: (202) 482-2440.

#### SUPPLEMENTARY INFORMATION:

##### Background

On May 6, 1995, President Clinton issued Executive Order 12959 (60 FR 24757), imposing significant new economic sanctions on Iran. The effective date of the Executive Order was May 7, 1995 at 12:01 EDT, except that an effective date of June 6, 1995, 12:01 a.m. EDT applied for exports and reexports under contracts that were entered into prior to May 7, 1995, and that were authorized pursuant to regulations in force immediately prior to May 6, 1995. The Department of the

Treasury's Office of Foreign Assets Control (OFAC) has responsibility for implementing the Executive Order, including issuing licenses for exports and certain reexports to Iran. (See OFAC's Iranian Transactions Regulations, 31 CFR part 560.) If OFAC authorizes an export or reexport, no separate authorization from BXA is necessary. This rule makes clear that enforcement action may be taken under the EAR with respect to an export or reexport prohibited both by the EAR and by the Executive Order and not authorized by OFAC.

Although the Export Administration Act (EAA) expired on August 20, 1994, the President invoked the International Emergency Economic Powers Act and continued in effect, to the extent permitted by law, the provisions of the EAA and the EAR in Executive Order 12924 of August 19, 1994, as extended by the President's notice of August 15, 1995 (60 Fed. Reg. 42767).

#### Rulemaking Requirements

1. This final rule has been determined to be not significant for purposes of E.O. 12866.

2. This rule involves collections of information subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). These collections have been approved by the Office of Management and Budget under control numbers 0694-0005, 0694-0007, and 0694-0010. Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number.

3. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

4. The provisions of the Administrative Procedure Act requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military and foreign affairs function of the United States (see 5 U.S.C. 553(a)(1)). Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule.

Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Hillary Hess, Office of Exporter Services, Regulatory Policy Division, Bureau of Export Administration, Department of Commerce, P.O. Box 273, Washington, DC 20044.

5. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under 5 U.S.C. 553(a)(1) or by any other law, under sections 3(a) and 4 (a) of the Regulatory Flexibility Act (5 U.S.C. 603(a) and 604(a)) no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

#### List of Subjects in 15 CFR Part 785

##### Exports.

Accordingly, Part 785 of the Export Administration Regulations (15 CFR Parts 730-799) is amended as follows:

1. The authority citation for 15 CFR Part 785 continues to read as follows:

Authority: Pub. L. 90-351, 82 Stat. 197 (18 U.S.C. 2510 *et seq.*), as amended; Pub. L. 95-223, 91 Stat. 1626 (50 U.S.C. 1701 *et seq.*); Pub. L. 95-242, 92 Stat. 120 (22 U.S.C. 3201 *et seq.* and 42 U.S.C. 2139a); Pub. L. 96-72, 93 Stat. 503 (50 U.S.C. App. 2401 *et seq.*), as amended; Pub. L. 102-484, 106 Stat. 2575 (22 U.S.C. 6004); E.O. 12002 of July 7, 1977 (42 FR 35623, July 7, 1977), as amended; E.O. 12058 of May 11, 1978 (43 FR 20947, May 16, 1978); E.O. 12214 of May 2, 1980 (45 FR 29783, May 6, 1980); E.O. 12730 of September 30, 1990 (55 FR 40373, October 2, 1990), as continued by Notice of September 25, 1992 (57 FR 44649, September 28, 1992); E.O. 12924 of August 19, 1994 (59 FR 43437, August 23, 1994); E.O. 12938 of November 14, 1994 (59 FR 59099 of November 16, 1994); E.O. 12957 of March 15, 1995 (60 FR 14615 of March 17, 1995); E.O. 12959 of May 6, 1995 (60 FR 24757 of May 9, 1995); and Notice of August 15, 1995, 60 FR 42767.

#### PART 785—[AMENDED]

2. Section 785.4 is amended by adding paragraph (b) to read as follows:

##### § 785.4 Country Groups T & V.

\* \* \* \* \*

##### (b) Iran.

Note: The Treasury Department's Office of Foreign Assets Control (OFAC) administers a comprehensive trade and investment embargo against Iran under the authority of the International Emergency Economic

Powers Act of 1977, as amended, section 505 of the International Security and Development Cooperation Act of 1985, and Executive Orders 12957 and 12959 of March 15, 1995 and May 6, 1995, respectively. This embargo includes prohibitions on export and certain reexport transactions involving Iran, including transactions dealing with items subject to the EAR. (See OFAC's Iranian Transactions Regulations, 31 CFR part 560.)

(1) The controls on exports and reexports to Iran, as specified in the CCL and in paragraph (d) of this section, continue to apply. To avoid duplication, exporters or reexporters are not required to seek separate authorization from BXA for an export or reexport subject both to the EAR and to OFAC's Iranian Transactions Regulations. Therefore, if OFAC authorizes an export or reexport, no separate authorization from BXA is necessary.

(2) Section 3 of the Executive Order directs all agencies of the United States Government to take all appropriate measures within their jurisdiction to carry out the order. Accordingly, no validated license, general license or other authorization constitutes authority for any export or reexport prohibited by the Iranian Transactions Regulations unless authorized by OFAC, and no person may export or reexport items subject to both the EAR and OFAC's Iranian Transactions Regulations without prior OFAC authorization. Any export or reexport prohibited both by the EAR and by the Executive Order and not authorized by OFAC is a violation of the EAR.

(3) Exporters should consult with OFAC (Office of Foreign Assets Control, U.S. Department of the Treasury, 1500 Pennsylvania Avenue, N.W., Annex, 2nd Floor, Washington, D.C. 20220. Telephone (202) 622-2480) for authorization for:

- (i) Exports from the United States involving Iran;
- (ii) Exports or reexports to Iran from a third country, when the exporter or reexporter is a United States person (as defined in OFAC's Iranian Transactions Regulations, 31 CFR part 560); or
- (iii) Reexports to Iran of U.S.-origin items that were subject to any export license application requirements prior to Executive Order 12959 of May 6, 1995.

(Office of Foreign Assets Control, U.S. Department of the Treasury, 1500 Pennsylvania Avenue, N.W., Annex, 2nd Floor, Washington, D.C. 20220. Telephone (202) 622-2480.)

\* \* \* \* \*

Dated: February 29, 1996.

Sue E. Eckert,

*Assistant Secretary for Export Administration.*

[FR Doc. 96-5103 Filed 3-4-96; 8:45 am]

BILLING CODE 3510-DT-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 5

#### Delegations of Authority and Organization; Technical Amendment

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the regulations for delegations of authority to set forth the current organizational structure of the agency as well as the current addresses for headquarters and field offices. This action is necessary to ensure accuracy of the regulations.

**EFFECTIVE DATE:** March 5, 1996.

**FOR FURTHER INFORMATION CONTACT:** Ellen Rawlings, Division of Management Systems and Policy (HFA-340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4976.

**SUPPLEMENTARY INFORMATION:** The regulations are being amended in 21 CFR 5.100 to reflect the current addresses for headquarters and for field and district offices.

Notice and comment on these amendments are not necessary under the Administrative Procedure Act because this is a rule of Agency organization (5 U.S.C. 553(b)).

#### List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

#### PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261-1282, 3701-3711a; secs. 2-12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451-1461); 21 U.S.C. 41-50, 61-63, 141-149, 467f, 679(b),

801-886, 1031-1309; secs. 201-903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 354, 361, 362, 1701-1706; 2101, 2125, 2127, 2128 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 2421, 242n, 243, 262, 263, 263b, 264, 265, 300u-300u-5, 300aa-1, 300aa-25, 300aa-27, 300aa-28); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007-10008; E.O. 11490, 11921, and 12591; secs. 312, 313, 314 of the National Childhood Vaccine Injury Act of 1986, Pub. L. 99-660 (42 U.S.C. 300aa-1 note).

#### § 5.100 [Amended]

2. Section 5.100 is amended by revising footnotes 9 and 12, and by adding new footnote 17 to the entry for "Division of Clinical Laboratory Devices." To read as follows:

#### § 5.100 Headquarters.

\* \* \* \* \*

Center for Biologics Evaluation and Research<sup>9</sup>

\* \* \* \* \*

Office of Device Evaluation<sup>12</sup>

\* \* \* \* \*

Division of Clinical Laboratory Devices<sup>17</sup>

\* \* \* \* \*

Dated: February 26, 1996.

William K. Hubbard,

*Associate Commissioner for Policy Coordination.*

[FR Doc. 96-4977 Filed 3-4-96; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF JUSTICE

### 28 CFR Part 52

[AG ORDER No. 2012-96]

RIN 1105-AA43

#### Revision of Policy Concerning Consent To Try Civil Matters Before Magistrate Judges

**AGENCY:** Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** The United States Department of Justice is publishing a final rule to revise and clarify Department policy concerning consent to try civil matters before magistrate judges.

**EFFECTIVE DATE:** This final rule is effective March 5, 1996.

**FOR FURTHER INFORMATION CONTACT:** Mary C. Morgan, Deputy Assistant Attorney General, Office of Policy

<sup>9</sup> Mailing address: 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448.

<sup>12</sup> Mailing address: 9200 Corporate Blvd., Rockville, MD 20850.

<sup>17</sup> See footnote 13.

Development, Department of Justice, Washington, DC 20530, telephone (202) 514-0052.

**SUPPLEMENTARY INFORMATION:** A working group consisting of representatives from senior Justice Department offices and litigating divisions and the United States Attorneys' Offices reviewed the Department's policy concerning consent to try civil matters before magistrate judges. As a result of this review, the Department reaffirms its existing policy of encouraging the use of magistrate judges to assist the district courts in resolving civil disputes whenever possible, as set forth in 28 CFR 52.01, but makes several clarifying changes.

Paragraphs (1) through (4) of § 52.01(a) merely summarize provisions of federal statutory and case law set forth elsewhere. This rule eliminates those paragraphs, thus streamlining the Code of Federal Regulations.

This rule deletes from § 52.01(b) the two sentences immediately following paragraph (7). The first sentence—referring to cases “involving significant rights of large numbers of persons, or complex, sensitive, or unusually important issues”—is unnecessary and inconsistent with existing Department policy set forth elsewhere in this Part. Instead, this rule amends § 52.01(b)(1) to include a reference to the involvement of significant rights of large numbers of persons as a factor to be considered relating to the complexity of the case.

The second sentence—referring to a formal consultation process with the appropriate Assistant Attorney General—is unnecessary given the large number of cases in which a consultation with the Assistant Attorney General is not required because redelegation authority has been exercised. This rule amends § 52.01(b) to require that the determination by the government attorney whether to consent to a trial before a magistrate judge simply be made “with the concurrence of his or her supervisor.” The rule retains the requirement currently existing in § 52.01(d), but incorporates it into § 52.01(c), for consultation with the appropriate Assistant Attorney General regarding consent to an appeal to the district court rather than to the court of appeals but deletes the phrase “to a trial before a magistrate.” The rule amends § 52.01(b) by adding the phrase “as set forth in this paragraph” to clarify that the determination is based upon consideration of all the enumerated factors.

This rule conforms the terminology of §§ 52.01 and 52.02 to the Judicial Improvements Act of 1990, Pub. L. 101-650, section 321, which changed the

designation of persons appointed under 28 U.S.C. 631 from United States magistrate to that of United States magistrate judge.

Administrative Procedure Act 5 U.S.C. 553

Because these regulations relate to agency management or personnel, the Department of Justice finds good cause for exempting them from the provision of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public comment, and delay in effective date.

#### Regulatory Flexibility Act

The Attorney General, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this final rule and, by approving it, certifies that this rule will not have a significant economic impact on a substantial number of small entities.

#### Executive Order 12866

This regulation has been drafted and reviewed in accordance with Executive Order 12866, section 1(b). The Attorney General has determined that this rule is not a significant regulatory action under Executive Order 12866, section 3(f), and, accordingly, this rule has not been reviewed by the Office of Management and Budget.

#### List of Subjects in 28 CFR Part 52

##### Courts.

Accordingly, for the reasons set forth in the preamble, part 52 of chapter I of Title 28 of the Code of Federal Regulations is amended as follows:

#### **PART 52—PROCEEDINGS BEFORE U.S. MAGISTRATE JUDGES**

1. The heading for Part 52 is revised to read as set forth above.

2. The authority citation for part 52 continues to read as follows:

Authority: 5 U.S.C. 301; 18 U.S.C. 3401(f).

3. Section 52.01 is revised to read as follows:

##### **§ 52.01 Civil proceedings: Special master, pretrial, trial, appeal.**

(a) Sections 636 (b) and (c) of title 28 of the United States Code govern pretrial and case-dispositive civil jurisdiction of magistrate judges, as well as service by magistrate judges as special masters.

(b) It is the policy of the Department of Justice to encourage the use of magistrate judges, as set forth in this paragraph, to assist the district courts in resolving civil disputes. In conformity with this policy, the attorney for the government is encouraged to accede to

a referral of an entire civil action for disposition by a magistrate judge, or to consent to designation of a magistrate judge as special master, if the attorney, with the concurrence of his or her supervisor, determines that such a referral or designation is in the interest of the United States. In making this determination, the attorney shall consider all relevant factors, including—

- (1) The complexity of the matter, including involvement of significant rights of large numbers of persons;
- (2) The relief sought;
- (3) The amount in controversy;
- (4) The novelty, importance, and nature of the issues raised;
- (5) The likelihood that referral to or designation of the magistrate judge will expedite resolution of the litigation;
- (6) The experience and qualifications of the magistrate judge; and
- (7) The possibility of the magistrate judge's actual or apparent bias or conflict of interest.

(c) (1) In determining whether to consent to having an appeal taken to the district court rather than to the court of appeals, the attorney for the government should consider all relevant factors including—

- (i) The amount in controversy;
- (ii) The importance of the questions of law involved;
- (iii) The desirability of expeditious review of the magistrate judge's judgment.

(2) In making a determination under paragraph (c)(1) of this section the attorney shall, except in those cases in which delegation authority has been exercised under 28 CFR 0.168, consult with the Assistant Attorney General having supervisory authority over the subject matter.

#### **§ 52.02 [Amended]**

4. Section 52.02 is amended by removing the word “magistrate” wherever it appears and adding, in its place, “magistrate judge” and by removing the word “magistrate's” wherever it appears and adding, in its place, “magistrate judge's”.

Dated: February 26, 1996.

Janet Reno,

*Attorney General.*

[FR Doc. 96-4927 Filed 3-4-96; 8:45 am]

BILLING CODE 4410-01-M

**FEDERAL EMERGENCY  
MANAGEMENT AGENCY****44 CFR Part 64**

[Docket No. FEMA-7636]

**Suspension of Community Eligibility****AGENCY:** Federal Emergency Management Agency, FEMA.**ACTION:** Final rule.

**SUMMARY:** This rule identifies communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are suspended on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will be withdrawn by publication in the Federal Register.

**EFFECTIVE DATES:** The effective date of each community's suspension is the third date ("Susp.") listed in the third column of the following tables.

**ADDRESSES:** If you wish to determine whether a particular community was suspended on the suspension date, contact the appropriate FEMA Regional Office or the NFIP servicing contractor.

**FOR FURTHER INFORMATION CONTACT:** Robert F. Shea Jr., Division Director, Program Implementation Division, Mitigation Directorate, 500 C Street, SW., Room 417, Washington, DC 20472, (202) 646-3619.

**SUPPLEMENTARY INFORMATION:** The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the National Flood Insurance Program, 42 U.S.C. 4001 et seq., unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59 et seq. Accordingly, the communities

will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. However, some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of the communities will be published in the Federal Register.

In addition, the Federal Emergency Management Agency has identified the special flood hazard areas in these communities by publishing a Flood Insurance Rate Map (FIRM). The date of the FIRM if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may legally be provided for construction or acquisition of buildings in the identified special flood hazard area of communities not participating in the NFIP and identified for more than a year, on the Federal Emergency Management Agency's initial flood insurance map of the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column.

The Acting Associate Director finds that notice and public comment under 5 U.S.C. 553(b) are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives a 6-month, 90-day, and 30-day notification addressed to the Chief Executive Officer that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications have been made, this final rule may take effect within less than 30 days.

**National Environmental Policy Act**

This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Considerations. No environmental impact assessment has been prepared.

**Regulatory Flexibility Act**

The Acting Associate Director has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless they take remedial action.

**Regulatory Classification**

This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

**Paperwork Reduction Act**

This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq.

**Executive Order 12612, Federalism**

This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, October 26, 1987, 3 CFR, 1987 Comp., p. 252.

**Executive Order 12778, Civil Justice Reform**

This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778, October 25, 1991, 56 FR 55195, 3 CFR, 1991 Comp., p. 309.

**List of Subjects in 44 CFR Part 64**

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

**PART 64—[AMENDED]**

1. The authority citation for Part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 et seq.; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

**§ 64.6 [Amended]**

2. The tables published under the authority of § 64.6 are amended as follows:



State/location	Community No.	Effective date of eligibility	Current effective map date	Date certain Federal assistance no longer available in special flood hazard areas
<b>Region VI</b>				
Texas: Terrell, city of, Kaufman County .....	480416	June 18, 1976, Emerg; Sept. 30, 1980, Reg; Mar. 4, 1996, Susp.	03-04-96	Mar. 4, 1996.
<b>Region II</b>				
New York: Clarence, town of, Erie County .....	360232	Apr. 4, 1975, Emerg; Apr. 1, 1982, Reg; Mar. 5, 1996, Susp.	03-05-96	Mar. 5, 1996.
<b>Region III</b>				
Pennsylvania:				
Fayette City, borough of, Fayette County ...	420464	July 30, 1975, Emerg; Feb. 3, 1982, Reg; Mar. 5, 1996, Susp.	12-19-95	Do.
North Charleroi, borough of, Washington County.	422137	Dec. 13, 1974, Emerg; July 16, 1981, Reg; Mar. 5, 1996, Susp.	.....do	Do.
West Virginia:				
Bath, town of, Morgan County .....	540005	May 20, 1975, Emerg; Jan. 20, 1980, Reg; Mar. 5, 1996, Susp.	03-05-96	Do.
Morgan County, unincorporated areas .....	540144	Oct. 28, 1975, Emerg; July 1, 1987, Reg; Mar. 5, 1996, Susp.	.....do	Do.
Paw Paw, town of, Morgan County .....	540252	Oct. 2, 1975, Emerg; Nov. 2, 1984, Reg; Mar. 5, 1996, Susp.	.....do	Do.
<b>Region V</b>				
Indiana: Tipton, city of, Tipton County .....	180255	Oct. 29, 1975, Emerg; Mar. 5, 1996, Reg; Mar. 5, 1996, Susp.	.....do	Do.
Michigan:				
Plymouth, city of, Wayne County .....	260236	Aug. 6, 1975, Emerg; Feb. 18, 1981, Reg; Mar. 5, 1996, Susp.	01-05-96	Do.
Plymouth, Charter township of, Wayne County.	260237	Aug. 6, 1975, Emerg; Mar. 2, 1981, Reg; Mar. 5, 1996, Susp.	.....do	Do.
Minnesota:				
Aitkin County, unincorporated areas .....	270628	Apr. 23, 1974, Emerg; Mar. 15, 1982, Reg; Mar. 5, 1996, Susp.	02-02-96	Do.
Hopkins, city of, Hennepin County .....	270166	May 2, 1974, Emerg; May 5, 1981, Reg; Mar. 5, 1996, Susp.	12-19-95	Do.
Wisconsin:				
Cadott, village of, Chippewa County .....	550043	Jan. 23, 1975, Emerg; Mar. 5, 1996, Reg; Mar. 5, 1996, Susp.	03-05-96	Do.
Dane County, unincorporated areas .....	550077	Oct. 20, 1972, Emerg; Sept. 29, 1978, Reg; Mar. 5, 1996, Susp.	.....do	Do.
Madison, city of, Dane County .....	550083	July 17, 1975, Emerg; Sept. 30, 1980, Reg; Mar. 5, 1996, Susp.	.....do	Do.
Middleton, city of, Dane County .....	550087	June 27, 1974, Emerg; May 1, 1980, Reg; Mar. 5, 1996, Susp.	.....do	Do.
<b>Region VI</b>				
Louisiana: Duson, town of, Lafayette County ....	220104	Nov. 11, 1975, Emerg; Sept. 30, 1981, Reg; Mar. 5, 1996, Susp.	02-02-96	Do.

Code for reading third column: Emerg.—Emergency; Reg.—Regular; Rein.—Reinstatement; Susp.—Suspension.

(Catalog of Federal Domestic Assistance No. 83.100, "Flood Insurance.")

Issued: February 27, 1996.

Richard W. Krimm,  
Acting Associate Director, Mitigation  
Directorate.

[FR Doc. 96-5088 Filed 3-4-96; 8:45 am]

BILLING CODE 6718-05-P

## FEDERAL COMMUNICATIONS COMMISSION

**47 CFR Parts 0, 2, 5, 21, 22, 23, 25, 73, 78, 80, 90, 94, and 95**

[FCC 95-423]

### Reorganization of the Compliance and Information Bureau

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This action restructures the Compliance and Information Bureau. The Commission reviewed the

operations of the Bureau in light of principles of the National Performance Review to makes its operations more cost effective and to privatize those that could be handled by the private sector. It is the intent of this action to improve service to the public at a reduced cost.

**EFFECTIVE DATE:** February 9, 1996.

**FOR FURTHER INFORMATION CONTACT:** Wayne T. McKee, Compliance and Information Bureau, Federal Communications Commission, Washington, D.C. 20554, (202) 418-1191.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's *Order*,

FCC 95-423, adopted October 6, 1995, and released, February 9, 1996. The full text of this Order is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239) 1919 M Street, NW, Washington, DC. The complete text may be purchased from the Commission's copy contractor, International Transcription Services, 2100 M Street NW, Washington, DC 20037, telephone (202) 857-3800.

#### Summary of Order

1. The Commission completed a full review of the mission, processes, and organization of the Compliance and Information Bureau and has determined to make changes to them in order to create a more effective organization within the limits of our budgetary constraints.

2. The Commission will automate the high frequency direction-finding network by installing new technology which can be remotely-controlled from a single office. The Commission will also establish a complaint and inquiry intake center, with a toll-free (800 or 888) number, to centralize and make more efficient agency provision of information and processing of complaints. The Commission will close its offices in Buffalo, New York; Miami, Florida; St. Paul, Minnesota; Norfolk, Virginia; Portland, Oregon; Houston, Texas; San Juan, Puerto Rico; Anchorage, Alaska; and Honolulu, Hawaii. Two technical staff will be retained in each of these cities as resident enforcement agents. The remaining offices will be fully staffed and equipped to maintain the Commission's Enforcement program.

3. The amendments adopted pertain to agency organization, procedure, and practice. Consequently, the requirement of notice and comment and the effective date provisions of the Administrative Procedures Act, 5 U.S.C. § 553(b), (d), do not apply.

4. Authority for the amendments adopted is contained in Sections 4(i), 5(b), 5(c)(1) and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. §§ 154(i), 155(b), 155(c)(1), 303(r).

#### List of Subjects

##### 47 CFR Part 0

Organization and functions (Government agencies), Delegation of authority.

##### 47 CFR Part 2

Communications equipment, Imports.

##### 47 CFR Part 5

Monitoring stations, Radio.

##### 47 CFR Part 21

Monitoring stations, Radio.

##### 47 CFR Part 22

Monitoring stations, Radio.

##### 47 CFR Part 23

Monitoring stations, Radio.

##### 47 CFR Part 25

Monitoring stations, Radio.

##### 47 CFR Part 73

Monitoring stations, Radio broadcasting.

##### 47 CFR Part 78

Monitoring stations, Radio.

##### 47 CFR Part 80

Communications equipment, Inspections, Marine safety, Monitoring Stations, Overtime Compensation, Radio, Telegraph, Telephone, Vessels.

##### 47 CFR Part 90

Monitoring stations, Radio.

##### 47 CFR Part 94

Monitoring stations, Radio.

##### 47 CFR Part 95

Monitoring stations, Radio.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

#### Final Rules

Title 47 of the Code of Federal Regulations, Parts 0, 2, 5, 21, 22, 23, 25, 73, 78, 80, 90, 94, and 95 are amended as follows:

#### PART 0—COMMISSION ORGANIZATION

1. The authority citation for Part 0 continues to read as follows:

Authority: Secs. 5, 48 Stat. 1068, as amended: 47 U.S.C. 155

2. Section 0.5 is amended by adding paragraph (a)(15) to read as follows:

#### § 0.5 General description of Commission organization and operations.

(a) \* \* \*

(15) Compliance and Information Bureau.

\* \* \* \* \*

3. Section 0.111 and its preceding centered heading are revised to read as follows:

Compliance and Information Bureau

#### § 0.111 Functions of the Bureau.

(a) Enforce the Commission's Rules and Regulations; provide support to other governmental units, investigate all non-government communications matters; issue sanctions.

(b) Disseminate to the public on a local basis information regarding communications issues and Commission rules, policies, and programs.

(c) Collect information through a customer intelligence network to inform the Commission on the needs of its customer and on the impact of regulations and necessary refinements to them as suggested by the users and the public.

(d) Participate in international conferences dealing with monitoring and measurement; serve as the point of contact for the U.S. Government in matters of international monitoring, fixed and mobile direction-finding, and interference resolution. Provide technical and administrative support on the administration of the ITU Fellowship program and oversee coordination of non-routine communications and materials between the Commission and international or regional public organizations or foreign administrations.

(e) Reduce or eliminate interference to authorized communications. Promote private sector solutions to interference problems; investigate and resolve those unsuitable for private sector resolution or where the private sector is unable to provide solutions. Work, in conjunction with the Office of Engineering and Technology, with technical standards bodies.

(f) Perform investigations in support of Commission policies.

(g) Maintain, operate, and manage the toll-free telephone receiving center for complaint and inquiries. Coordinate with the Office of Public Affairs and maintain liaison with the rest of the agency to ensure that the needs of the public for information are handled promptly, accurately, and comprehensively and that complaints are directed to those charged with acting upon them.

(h) Under the general direction of the Defense Commissioner, coordinate the defense activities of the Commission, and provide support to the Defense Commissioner in his participation in the Joint Telecommunication Resources Board and the National Security Telecommunications Advisory Committee, including recommendation of national emergency plans and preparedness programs covering

Commission functions during national emergencies. Support the Chief, Common Carrier Bureau on assignment of Telecommunications Service Priority System priorities and the administration of this system. The Chief, Compliance and Information Bureau, or the designee of that person, acts as the FCC Defense Coordinator and the principal of the Commission to the National Communications System.

4. Section 0.185 is amended by revising the introductory text and paragraphs (a) and (b) to read as follows:

**§ 0.185 Responsibilities of the bureaus and staff offices.**

The head of each of the bureaus and staff offices, in rendering assistance to the Chief, Compliance and Information Bureau in the performance of that person's duties with respect to defense activities will have the following duties and responsibilities:

(a) To keep the Chief, Compliance and Information Bureau informed of the investigation, progress, and completion of programs, plans, or activities with respect to defense in which they are engaged or have been requested to engage.

(b) To render assistance and advice to the Chief, Compliance and Information Bureau on matters which relate to the functions of their respective bureaus or staff offices.

\* \* \* \* \*

5. Section 0.284(a)(3) and (a)(4) are revised to read as follows:

**§ 0.284 Actions taken under delegated authority.**

(a) \* \* \*

(3) Requests for waiver of tower painting and lighting specifications—Wireless Telecommunications Bureau.

(4) Matters involving emergency communications, including the issuance of Emergency Alert System Authorizations (FCC Form 392)—Compliance and Information Bureau.

\* \* \* \* \*

**§ 0.311 [Amended]**

6. Section 0.311 is amended by removing the words, "Chief, Field Operations Bureau, or his designee," and adding in their place, "Chief, Compliance and Information Bureau, or that person's designee," wherever they occur and by removing the words, "Field Operations Bureau" and adding in their place "Compliance and Information Bureau" wherever they occur.

**§ 0.445 [Amended]**

7. Section 0.445(g) is amended by removing the words, "FOB Manual" and

adding in their place, "CIB Manual" wherever they occur and by removing the words, "Field Operations Bureau" and adding in their place, "Compliance and Information Bureau" wherever they occur.

**§§ 0.15, 0.91, 0.121, 0.317, 0.332, 0.387, 0.401, 0.431, 0.443 [Amended]**

8. Sections 0.15(i), 0.91(l), 0.121(a), 0.317, 0.332(d), 0.332(h), 0.387(b), 0.401(a)(4), 0.431, and 0.443 are amended by removing the words "Field Operations Bureau" and adding in their place, "Compliance and Information Bureau" wherever they occur.

**PART 2—FREQUENCY ALLOCATION AND RADIO TREATY MATTERS; GENERAL RULES AND REGULATIONS**

1. The authority citation for Part 2 continues to read as follows:

Authority: Sec. 4, 302, 303, and 307 of the Communications Act, as amended, 47 U.S.C. Sections 154, 302, 303, and 307, unless otherwise noted.

2. Section 2.1204(a)(4) is amended by revising the third sentence to read as follows:

**§ 2.1204 Import conditions.**

(a) \* \* \*

(4) \* \* \* Prior to importation of more than ten units, written approval must be obtained from the Chief, Compliance Division, Compliance and Information Bureau, FCC. \* \* \*

\* \* \* \* \*

**PART 5—EXPERIMENTAL RADIO SERVICES (OTHER THAN BROADCAST)**

1. The authority citation for Part 5 continues to read as follows:

Authority: Secs. 4, 303, 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 303. Interpret or imply sec. 301, 48 Stat. 1081, as amended; 47 U.S.C. 301.

**§ 5.67 [Amended]**

2. Section 5.67(d)(2) is amended by removing the words, "Field Operations Bureau" and adding in their place, "Compliance and Information Bureau" wherever they occur.

**PART 21—DOMESTIC PUBLIC FIXED RADIO SERVICES**

1. The authority citation for Part 21 continues to read as follows:

Authority: Secs. 1, 2 4, 201–205, 208, 215, 218, 303, 307, 313, 403, 404, 410, 602, 48 Stat. as amended, 1064, 1066, 1070–1073, 1076, 1077, 1080, 1082, 1083, 1087, 1094, 1098, 1102; 47 U.S.C. 151, 154, 201–205, 208, 215, 218, 303, 307, 313, 314, 403, 404, 602; 47 U.S.C. 552, 554.

**§ 21.113 [Amended]**

2. Section 21.113(c)(2) is amended by removing the words, "Field Operations Bureau" and adding in their place, "Compliance and Information Bureau" wherever they occur.

**PART 22—PUBLIC MOBILE SERVICE**

1. The authority citation for Part 22 continues to read as follows:

Authority: 47 U.S.C. 154, 303, unless otherwise noted.

**§ 22.369 [Amended]**

2. Section 22.369(c)(3) is amended by removing the words, "Field Operations Bureau" and adding in their place, "Compliance and Information Bureau" wherever they occur.

**PART 23—INTERNATIONAL FIXED PUBLIC RADI COMMUNICATIONS SERVICES**

1. The authority citation for Part 23 continues to read as follows:

Authority: Secs. 4, 303, 48 Stat. 1066, 1082 as amended; 47 U.S.C. 154, 303. Interpret or apply sec. 301, 48 Stat. 1081; 47 U.S.C. 301.

**§ 23.20 [Amended]**

2. Section 23.20(e)(2) is amended by removing the words, "Field Operations Bureau" and adding in their place, "Compliance and Information Bureau" wherever they occur.

**PART 25—SATELLITE COMMUNICATIONS**

1. The authority citation for Part 25 continues to read as follows:

Authority: Secs. 25.101 to 25.601 issued under Sec. 4, 48 Stat. 1066, as amended; 47 U.S.C. 154. Interpret or apply secs. 101–104, 76 Stat. 419–427; 47 U.S.C. 701–744; 47 U.S.C. 554.

**§ 25.203 [Amended]**

2. Section 25.203(g)(2) is amended by removing the words, "Field Operations Bureau" and adding in their place, "Compliance and Information Bureau" wherever they occur.

**PART 73—RADIO BROADCAST SERVICES**

1. The authority citation for Part 73 to read as follows:

Authority: 47 U.S.C. 154, 303, 334.

**§ 73.1030 [Amended]**

2. Section 73.1030(c)(2) is amended by removing the words, "Field Operations Bureau" and adding in their place, "Compliance and Information Bureau" wherever they occur.

**PART 78—CABLE TELEVISION RELAY SERVICE**

1. The authority citation for Part 78 continues to read as follows:

Authority: Secs. 2, 3, 4, 301, 303, 307, 308, 309, 48 Stat., as amended, 1064, 1065, 1066, 1081, 1082, 1083, 1084, 1085; 47 U.S.C. 152, 153, 154, 301, 303, 307, 308, 309.

**§ 78.19 [Amended]**

2. Section 78.19(e)(2) is amended by removing the words, "Field Operations Bureau" and adding in their place, "Compliance and Information Bureau" wherever they occur.

**PART 80—STATIONS IN THE MARITIME SERVICES**

1. The authority citation for Part 80 continues to read as follows:

Authority: Secs. 4, 303, 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 303, unless otherwise noted. Interpret or apply 48 Stat. 1064–1068, 1081–1105, as amended; 47 U.S.C. 151–155, 301–609; 3 UST 3450, 3 UST 4726, 12 UST 2377.

**§ 80.21 [Amended]**

2. Sections 80.21(b)(1) and 80.59(e) are amended by removing the words, "Field Operations Bureau" and adding in their place, "Compliance and Information Bureau" wherever they occur.

**PART 90—PRIVATE LAND MOBILE RADIO SERVICES**

1. The authority citation for Part 90 continues to read as follows:

Authority: Sections 4, 303, and 332, 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 303, and 332, unless otherwise noted.

**§ 90.177 [Amended]**

2. Section 90.177(d)(2) is amended by removing the words, "Field Operations Bureau" and adding in their place, "Compliance and Information Bureau" wherever they occur.

**PART 94—PRIVATE OPERATIONAL-FIXED MICROWAVE SERVICE**

1. The authority citation for Part 94 continues to read as follows:

Authority: Sections 4, 303, 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 303, unless otherwise noted.

**§ 94.25 [Amended]**

2. Section 94.25(i)(2) is amended by removing the words, "Field Operations Bureau" and adding in their place, "Compliance and Information Bureau" wherever they occur.

**PART 95—PERSONAL RADIO SERVICES**

1. The authority citation for Part 95 continues to read as follows:

Authority: Secs. 4, 303, 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 303.

**§ 95.39 [Amended]**

2. Section 95.39 is amended by removing the words, "Field Operations Bureau" and adding in their place, "Compliance and Information Bureau" wherever they occur.

[FR Doc. 96–5041 Filed 3–4–96; 8:45 am]

BILLING CODE 6712–01–P

**47 CFR Part 90**

[PR Docket No. 93–35; FCC 96–53]

**Channel Exclusivity to Qualified Private Paging Systems at 929–930 MHz**

**AGENCY:** Federal Communications Commission.

**ACTION:** Final Rule.

**SUMMARY:** In this *Memorandum Opinion and Order*, the Commission reviews six petitions for reconsideration and/or clarification of the *PCP Exclusivity Order* in this docket establishing channel exclusivity for qualified local, regional, and nationwide paging systems in the 929–930 MHz band, and grants the petitions in part and denies them in part. The petitions requesting exclusivity to regional 929 MHz systems in regions defined by state borders, rather than based on their actual service areas, are denied. The petitions that seek to increase the maximum transmitter power for local and regional systems are granted. Additionally, the Commission partially grants certain pending waiver requests of incumbent licensees seeking additional time to comply with multi-frequency transmitter specifications. The intended effect of this order is to affirm that exclusivity to regional 929 MHz systems is granted based on the service area as set forth in the *PCP Exclusivity Order* and to amend the rules to facilitate the rapid and efficient licensing of paging in the 929–930 MHz band. These amendments to the regional channel exclusivity scheme established in the *PCP Exclusivity Order* will facilitate the development of seamless, wide-area 900 MHz paging systems.

**EFFECTIVE DATE:** April 4, 1996.

**FOR FURTHER INFORMATION CONTACT:** Mika Savir, Commercial Wireless Division, Wireless Telecommunications Bureau, at (202) 418–0620.

**SUPPLEMENTARY INFORMATION:** This *Memorandum Opinion and Order* in PR Docket No. 93–35; RM Docket 7986, adopted February 8, 1996, and released February 13, 1996, is available for inspection and copying during normal business hours in the FCC Dockets Branch, Room 230, 1919 M Street N.W., Washington D.C. The complete text may be purchased from the Commission's copy contractor, International Transcription Service, Inc., 2100 M Street N.E., Suite 140, Washington D.C. 20037 (202) 857–3800.

Synopsis of Memorandum Opinion and Order

**I. Introduction**

Before the Commission are six petitions for reconsideration and/or clarification of our *PCP Exclusivity Order*, Amendment of the Commission's Rules to Provide Channel Exclusivity to Qualified Private Paging Systems at 929–930 MHz, *Report and Order*, PR Docket No. 93–35, 58 FR 62289 (November 26, 1993) (*PCP Exclusivity Order*), establishing channel exclusivity for qualified local, regional, and nationwide paging systems in the 929–930 MHz band. After reviewing the issues involved, the Commission grants the petitions in part and denies them in part. In particular, the Commission denies petitions requesting that exclusivity be granted to regional 929 MHz systems in regions defined by state borders, rather than based on their actual service areas. The Commission partially grants those petitions that seek to increase the maximum transmitter power for local and regional systems. The Commission also partially grants certain pending waiver requests of incumbent licensees seeking additional time to comply with the multi-frequency transmitter specifications. The Commission otherwise affirms the rules governing 929 MHz private paging as adopted in the *PCP Exclusivity Order*.

Additionally, the Commission is adopting a *Notice of Proposed Rule Making* in WT Docket No. 96–18, 61 FR 6199 (February 16, 1996) to examine ways to promote continued growth of the paging industry. In the *Notice of Proposed Rulemaking*, the Commission proposes to adopt new rules providing that future licensing of all exclusive paging channels, including 929 MHz channels, will be based on market-defined service areas, with mutually exclusive applications to be resolved by competitive bidding. Therefore, the conclusions reached in this *Memorandum Opinion and Order* are subject to future modification based on

the outcome of the comprehensive paging rulemaking.

## II. Background

**PCP Exclusivity Order.** In the *PCP Exclusivity Order*, the Commission implemented a system of exclusive licensing for qualified local, regional, and nationwide 929 MHz private paging systems on 35 of 40 available channels. Prior to this action, all private paging frequencies, including those at 929 MHz, were assigned on a non-exclusive basis. The *PCP Exclusivity Order* concluded that enabling 929 MHz paging systems to operate on an exclusive basis is in the public interest, due to the efficiencies and incentives such an approach encourages in the marketplace. Specifically, the Commission indicated that continued sharing of frequencies would undermine efficient use of 929 MHz paging channels as demand for paging services expands in the future. The Commission observed that, while sharing is technically feasible, dividing air time among multiple licensees imposes significant constraints on the efficiency and quality of service in crowded markets. The Commission also indicated that in a shared environment, licensees are reluctant to invest in advanced paging technology because of the risk that others will be assigned to the same frequency in the future. The Commission concluded that exclusivity would create a stable, predictable environment necessary for the industry to attract investment in wide-area, high capacity paging systems in the 929–930 MHz band.

The *PCP Exclusivity Order* established the requirements for licensees to obtain channel exclusivity in the 929 MHz band. In particular, the Commission established minimum standards for the configuration of protected systems, including the number of transmitters required for local, regional, and nationwide systems, and the treatment of multi-frequency transmitters. The Commission also implemented geographic separation standards for placement of co-channel stations, to protect qualified local or regional systems, and established effective radiated power (ERP) limits for all such systems.

The *PCP Exclusivity Order* also set forth other prerequisites to obtaining exclusivity. Most notably, the Commission conditioned exclusivity on construction of a qualified system within eight months of licensing. For larger systems, the Commission indicated that a new applicant may request an extension of up to three years, based on its showing of need, a

construction timetable, and its establishment of an escrow account or securing of a performance bond to cover construction costs. Other matters addressed in the *PCP Exclusivity Order* include issues associated with application of exclusivity to existing systems and to future licensing, and certain transitional procedures. In particular, the Commission grandfathered all existing systems and indicated that it would grant immediate exclusivity to existing systems that satisfied the new exclusivity criteria.

**Petitions for Reconsideration/Waivers.** The Commission received petitions for reconsideration of the *PCP Exclusivity Order* from the following businesses and organizations: (1) the National Association of Business and Educational Radio and its Association for Private Carrier Paging Section (NABER); (2) First American National Paging (First National); (3) Afro-American Paging, Inc. (AAP); (4) American Mobilephone, Inc. (AMI); (5) Paging Network, Inc. (PageNet); MAP Mobile Communications, Inc. (MAP); and (6) Metrocall, Inc. The Commission has sought and received comment on the issues raised by these petitions. Some parties also have filed petitions asking that various provisions of the new exclusivity rules be waived to accommodate specific hardship situations. These requests generally involve waiver of the construction requirements, ERP limits, or system configuration rules. For the most part, the Commission will decide these waiver requests in other proceedings. The Commission partially grants the waiver requests of certain grandfathered licensees seeking time to convert their systems from multi-frequency transmitter to single-frequency transmitter operations for exclusivity purposes.

## III. Discussion

### A. Configuration of Local Systems

**Background.** To qualify for channel exclusivity under the 929 MHz paging rules, the *PCP Exclusivity Order* provided that a local system must consist of at least six contiguous transmitters, except in the New York, Los Angeles, and Chicago markets, where 18 contiguous transmitters are required. The Commission also provided that transmitters will be considered contiguous if (1) each transmitter is located within 25 miles of at least one other transmitter in the system; (2) the combined area defined by a 12.5 mile radius around each transmitter forms a single contiguous area; and (3) no transmitter is co-located

with any other transmitter being counted as part of the local system.

**Petitions for Reconsideration/Comments.** On reconsideration, AAP challenges Section 90.495 (a)(1)(ii) of the rules, as adopted in the *PCP Exclusivity Order*, which requires that a 12.5 mile radius surrounding each transmitter form a single contiguous area. AAP argues that there was no notice of this rule change, because the restriction was not part of our original proposal and is not a logical outgrowth of the *PCP Exclusivity Notice*. Amendment of the Commission's Rules to Provide Channel Exclusivity to Qualified Private Paging Systems at 929–930 MHz, *Notice of Proposed Rulemaking*, PR Docket No. 93–35, 58 FR 17819 (April 6, 1993) (*PCP Exclusivity Notice*). AAP claims that as a result of the added 12.5 mile radius requirement, one of its systems now is disqualified from obtaining exclusivity. AAP contends that if it is the Commission's goal to confine systems to smaller geographic areas, a 15 mile radius standard is more equitable. The Commission has received no comments on AAP's reconsideration proposal.

**Decision.** The Commission will not eliminate or alter the requirement for local exclusivity that requires that a 12.5 mile radius surrounding each transmitter form a single contiguous area. The 12.5 mile rule is a necessary component of the exclusivity rules, because it ensures that a local system will serve a contiguous geographic area. Without such a requirement, licensees could obtain local exclusivity based on non-contiguous placement of transmitters, undermining the Commission's effort to establish truly local systems serving an indigenous locale or community. Proportionately, the 12.5 mile distance is one-half the distance of the 25 mile rule, and thereby works well to ensure that transmitters are located to serve a single contiguous geographic territory.

While the 12.5 mile rule was not expressly included in the *PCP Exclusivity Notice*, the Commission believes that this restriction nonetheless is a "sufficiently minor" difference from the rule proposed to be a "logical outgrowth" of the Commission's efforts to establish a system of local exclusivity. The *PCP Exclusivity Notice* sought comment on the configuration of locally protected systems. Specifically, the Commission proposed that each transmitter in a qualified system would have to be within 25 miles of another transmitter to count toward the number required for exclusivity. Incorporation of the 12.5 mile restriction in the final rules constitutes a minor, technical

change to the original proposal, which is necessary to ensure that local exclusivity is awarded to operators that locate transmitters in close proximity to one another within a system. The 12.5 mile rule effectively closes a loophole in the original proposal, and comports with the Commission's intent to create local paging systems in the 929–930 MHz band. Only AAP has objected to the change, apparently based on its own unique situation, that one of its transmitters is 13.2 miles from the nearest other transmitter, which is best resolved by a request for waiver.

#### B. Configuration of Regional Systems

**Background.** The *PCP Exclusivity Order* provided protection for exclusive regional systems based on the location of stations comprising the system. To qualify for exclusivity, a regional system must consist of 70 or more transmitters, not necessarily contiguous, located in no more than twelve adjacent states in the continental United States. The rules provide regional systems with exclusivity based on a prescribed separation distance around each of the regional licensee's stations, ranging from 112 to 187 kilometers (70 to 116 miles) depending on the class of the station. Also, in each of the top thirty markets, specified in Section 90.741 of the Commission's rules, no transmitter may be counted as part of a regional system unless it also meets the requirements for local exclusivity in that market. ***Petitions for Reconsideration/Comments.*** NABER and PageNet argue that the geographic scope of exclusivity granted to 929 MHz regional systems should be based on state borders, rather than the location of the system's stations. According to NABER, allowing regional paging systems statewide exclusivity in each state in which the system provides service is needed to promote the development of regional systems. NABER and PageNet also express concern that under the current rules, speculators can file applications in strategic locations designed solely to extract payment from regional systems seeking to expand their coverage. NABER therefore recommends that the Commission grant regional applicants (*i.e.*, applicants proposing a system of 70 or more transmitters) exclusivity extending to the borders of any state in which the applicant constructs at least one transmitter, except that in states having markets listed among the top 30, the applicant must construct six or 18 transmitters, depending on the size of the market. NABER also requests that the Commission permit regional licensees to locate transmitters

anywhere within any state included in the system, as long as they maintain the required geographic separation from facilities in adjoining regions.

AMI and ADC express concern about the application of NABER's proposal to licensees who are entitled to regional exclusivity under our existing rules. In general, these commenters are opposed to any change that would result in divesting licensees of existing exclusivity rights. ADC suggests that the Commission not apply statewide exclusivity to licensees whose applications (including those for local exclusivity) were received by NABER for coordination on or before March 31, 1994, at least where a portion of the involved local system was constructed and in operation before October 14, 1993.

ARCH, API, and Airtouch, on the other hand, favor statewide exclusivity for licensing as proposed by NABER and PageNet. According to these commenters, permitting licensees to achieve exclusivity on a statewide basis is essential to the development of truly regional systems. Airtouch and ARCH believe AMI and ADC's opposition to statewide exclusivity stems from the unique market situation of these licensees, and contend that the appropriate remedy for AMI and ADC is a waiver, not a decision to retain the status quo.

**Decision.** The Commission declines to reconsider the rules defining regional exclusivity for 929 MHz regional systems in this proceeding. The Commission is considering the issue of revising the paging licensing area definitions in a separate *Notice of Proposed Rule Making* on market-area licensing. Under the market-area licensing proposal, paging systems in general, including 929 MHz systems, no longer would be licensed on a station-by-station basis. Instead, licensees would be licensed within Commission-defined service areas, and would be afforded the same flexibility, to the extent feasible, as cellular and PCS licensees to locate, design, construct, and modify system facilities throughout those areas. Because the Commission is addressing this issue in a broader context than 929 MHz paging alone, it is premature to modify the rules for this single category of paging service in response to NABER's reconsideration petition.

Moreover, the Commission is not persuaded that paging licensing areas should be based on state borders, as NABER proposes. In all other services where Commission-defined licensing areas have been adopted, as opposed to station-by-station licensing, the

Commission has used licensing area definitions based on economic markets or trading areas (*e.g.*, MSAs/RSAs for cellular, and MTAs/BTAs for PCS and 900 MHz SMR). By contrast, using state borders would create licensing areas with political boundary lines which do not necessarily correspond to economic markets or trading areas and, in some instances, which may cut across them. The Commission therefore concludes that the status quo should prevail while alternative licensing area definitions more consistent with our approach in other services are considered.

#### C. Effective Radiated Power

**Background.** In the *PCP Exclusivity Order*, the Commission established effective radiated power (ERP) limits of 1000 watts for local and regional 929 MHz systems and 3500 watts for nationwide systems. The Commission noted that the 3500 watt limit for nationwide systems was the same as the limit for nationwide common carrier paging systems in the 931 MHz band. The Commission declined to adopt a 3500 watt limit for non-nationwide systems, notwithstanding the fact that the Part 22 rules then in effect allowed 931 MHz non-nationwide common carrier licensees to operate internal system sites at 3500 watts. The Commission reasoned that higher power limits for 931 MHz licensees were justified because demand for 931 MHz licenses largely was confined to expansion by existing systems. The Commission concluded that a 1000 watt maximum for 929 MHz non-nationwide systems was appropriate to preserve opportunities for entry by new systems.

***Petitions for Reconsideration/Comments.*** NABER and PageNet request that the Commission increase the maximum ERP for 929 MHz regional systems from 1000 watts to 3500 watts, provided that adjacent co-channel systems remain protected. NABER claims that, in the context of the statewide regional licensing scheme it has proposed, a 3500 watt power limit would not restrict opportunities for the entry of new systems into the market, which was the reason the Commission rejected a 3500 watt ERP previously. According to NABER and PageNet, use of high-power transmitters within the boundaries of a regional system will enable licensees to offer superior service at a lower cost. Celpage, ARCH, Airtouch, and API support NABER's proposal.

MAP seeks clarification on whether the 1000 watt ERP restriction applies only to facilities that define the exterior of the licensee's service area, and whether higher power facilities are

permitted at internal sites within existing service areas. MAP observes that 931 MHz common carrier paging licensees are permitted to operate at 3500 watts ERP at internal sites within their service areas. MAP asserts that principles of regulatory parity require us to apply the same rule to private paging systems. The Commission received no comments on MAP's request for clarification.

**Decision.** Except in certain limited circumstances discussed below, the Commission declines to raise the maximum ERP for non-nationwide 929 MHz systems at this time. NABER's proposal to raise the ERP limit is premised on the Commission adopting its proposal to base regional exclusivity on state borders, rather than site location. The Commission has declined to reconsider the definition of regional exclusivity, therefore NABER's rationale for raising the ERP limit does not apply. The Commission's decision on this issue does not preclude future changes to the rules if the Commission adopts some form of market-based licensing for 929 MHz channels. The Commission seeks further comment on height and power limits for common carrier and private carrier paging in the *Notice of Proposed Rule Making*.

The Commission agrees with commenters that under certain circumstances, allowing local and regional 929 MHz licensees to operate at greater than 1000 watts ERP may be appropriate. Specifically, if operation of sites at a higher power would not expand a licensee's existing service-area contour, there is no reason to prohibit operation at such higher power. The Commission will modify the rules to allow non-nationwide licensees to operate sites within their existing service area at up to 3500 watts ERP, provided that such operation does not increase the minimum geographic separation applicable to co-channel systems under Section 90.495(b)(2) of the Commission's rules. This will give licensees greater flexibility to build technically and economically efficient systems, without compromising opportunities for co-channel entry in areas adjacent to those systems.

#### D. Slow Growth Eligibility

**Background.** In the *PCP Exclusivity Order*, the Commission adopted rules allowing for so-called "slow growth" extensions of the eight-month construction requirement for larger system applicants. Specifically, for applications filed after October 14, 1993, a period of up to three years may be authorized for construction and commencement of operations if the

proposed system is composed of more than 30 transmitters and the applicant submits specific justification for an extended implementation period. Applicants must provide a detailed construction timetable and evidence of the ability to fund construction, either in the form of a construction escrow account or a performance bond covering construction costs.

**Petitions for Reconsideration/Comments.** NABER, PageNet, Metrocall, First National Paging, and AMI challenge the Commission's decision to make the three-year slow-growth option available only to post-October 14, 1993 paging applicants. NABER contends that the Commission did not provide adequate notice of the rule, because the *PCP Exclusivity Notice* did not expressly propose to limit the slow growth option to new applicants. According to NABER, the restriction has a detrimental impact on existing licensees because of the added construction demands posed by the Commission's treatment of multi-frequency transmitters under the exclusivity rules. AMI suggests that slow-growth eligibility be extended to licensees who filed for exclusivity after the March 31, 1993 release date of the *PCP Exclusivity Notice*, rather than limited to applicants filing after the October 14, 1993 date established in the *PCP Exclusivity Order*. According to AMI, there is no link between the October 14, 1993 date and the decision by any affected licensee to rebuild its facilities.

Commenters generally support extending the slow growth option to grandfathered licensees on the grounds that additional construction time is needed for incumbents to transition to our new system of channel exclusivity. Celpage, however, is concerned about the treatment of licensees who relied on single-frequency, as opposed to multi-frequency, transmitters. Celpage does not want operators that decided to build dedicated facilities at each licensed site, rather than to rely on inter-carrier agreements allowing them to utilize other licensees' dual-frequency transmitters, to be penalized under an extended transition period. Celpage therefore seeks reinstatement of certain "single use" transmitter licenses, whose authorizations expired while the exclusivity rules were under consideration. Arch and Airtouch support a slow growth period for existing licensees, but argue that the bond and escrow requirements for new construction should not apply in such cases.

**Decision.** The Commission will not change the rules to make pre-October 14, 1993 applicants automatically

eligible for the extended implementation construction schedule. October 14, 1993, the date of the *Sunshine Notice on the PCP Exclusivity Order*, is the cutoff date for slow growth eligibility. The Commission will deny slow growth extensions to grandfathered licensees generally. As of our *Sunshine Notice* on October 14, 1993, applicants reasonably could anticipate that the Commission was going to adopt channel exclusivity rules for 929–930 MHz paging licensees. To deter speculative filings, therefore, the Commission decided not to grandfather anyone that filed after October 14, 1993. The date for dividing "old" from "new" applicants also is the appropriate date for triggering slow growth eligibility. Moreover, the Commission never suggested that slow growth extensions would apply to grandfathered licensees. Indeed, in an April 6, 1993 *Order*, Amendment of the Commission's Rules to Provide Channel Exclusivity to Qualified Private Paging Systems at 929–930 MHz, *Order*, PR Docket No. 93–35, 58 FR 21111 (April 19, 1993) (*Order*), the Commission indicated that all parties in the application and coordination process were expected to comply with existing eight-month construction requirements while the rule making was underway. Consequently, applicants falling into the grandfathered category cannot legitimately claim that they expected to be eligible for slow growth extensions.

#### E. Multi-Frequency Transmitters

**Background.** In the *PCP Exclusivity Order*, the Commission considered the issue of whether licensees should be allowed to count multi-frequency transmitters for exclusivity purposes on more than one channel. The Commission concluded that licensees should not be barred from using multi-frequency transmitters, but that each such transmitter would be counted only once for exclusivity purposes. This requirement was to ensure that licensees would not claim exclusivity on multiple channels by repeatedly counting the same transmitter. The Commission noted that a licensee using multi-frequency transmitters could qualify for exclusivity on two frequencies by constructing twice the number of transmitters required to obtain one channel.

**Petitions for Reconsideration/Comments.** Several parties urge the Commission to relax the "single-count" rule to accommodate incumbent licensees who had constructed systems based on multi-frequency transmitters prior to the adoption of the *PCP Exclusivity Order*. NABER argues that these licensees need time to construct

sufficient single-frequency transmitters to comply with the exclusivity requirements on a single-count basis. PageNet suggests that existing licensees be given two years from the time they qualify for earned exclusivity to make this conversion. First National Paging suggests establishing a reasonable transition period for incumbent licensees, beyond the existing eight-month construction requirement.

In addition to reconsideration petitions on this issue, the Commission has received waiver requests from Arch, Comtech, First National Paging, Metrocall, Airtouch, and Message Center Beepers. At the time the *PCP Exclusivity Order* became effective, each of these petitioners was operating systems on dual channels using multi-channel transmitters. The number of transmitters in place in each system is sufficient to qualify for regional or nationwide exclusivity on one channel, but under the single-count rule petitioners would be required to construct additional sites to obtain protection for their operations on the second channel. Because their construction plans prior to the *PCP Exclusivity Order* relied on use of dual-channel transmitters, petitioners request twenty-four months rather than eight months to reconfigure their systems and construct additional sites to meet the requirements of the single-count rule.

**Decision.** The Commission declines to modify the general rule that no transmitter may be counted more than once for exclusivity purposes. This rule prevents the potential hoarding of multiple frequencies, by requiring paging licensees seeking more than one exclusive frequency to meet a higher construction threshold. Licensees may continue to use multi-frequency transmitters in their systems, but exclusivity will be conferred on multiple channels only if the total number of transmitters is sufficient to qualify for exclusivity on each channel on a single-count basis.

The Commission will grant some additional time to those grandfathered licensees who have filed waiver requests to bring existing systems into compliance with the single-count rule. Prior to the adoption of the *PCP Exclusivity Order*, these licensees had embarked on construction and operation of substantial systems relying on dual-frequency transmitters. The adoption of the single-count rule required these licensees to modify their plans to add additional transmitters in order to gain full exclusivity protection for their existing systems. The Commission believes that a reasonable time should be afforded to petitioners to make this

adjustment. The Commission notes that the risk of allowing hoarding of frequencies is not present here, because the systems at issue already are grandfathered on both channels, petitioners substantially have constructed their systems and are providing service to the public on a dual-channel basis, and the additional construction needed will promote increased coverage and better quality service.

The petitioners filed their initial requests for a twenty-four month construction period in early 1994. Since that time, petitioners have had substantial opportunity to construct additional facilities on a single-frequency transmitter basis to bring their systems into compliance. The Commission concludes that because of this elapsed time, petitioners should be granted an amount of time consistent with their original estimate of the time required to bring their systems into compliance. The Commission grants Arch, Comtech, First National Paging, Metrocall, Airtouch, and Message Center Beepers until six months after the publication date of this *Memorandum Opinion and Order* in the Federal Register to demonstrate that their grandfathered systems qualify for exclusivity on a single-count basis.

#### F. Modification of Existing Systems

**Background.** In the *PCP Exclusivity Order*, the Commission concluded that all existing 929 MHz licensees should be grandfathered under the new rules whether or not they qualified for exclusivity. Thus, incumbent systems that did not qualify for exclusivity would be allowed to continue operating their existing facilities, and any licensee granted exclusivity on the same channel in the same area would be required to share the channel with the grandfathered system. Grandfathered systems would not be allowed to add new facilities to their systems, however, if such expansion conflicted with exclusivity rights granted to another licensee.

**Petitions for Reconsideration/Comments.** MAP contends that the Commission should allow grandfathered licensees who do not qualify for exclusivity to modify their existing systems in order to continue service to subscribers. MAP argues that allowable modifications should include changes in the number of paging receivers, type of emission, antenna height, power, class of station, ownership or corporate structure, and location of existing facilities. API opposes MAP's proposal. API believes that minor and reasonable modifications to existing facilities

should be allowed, but that other changes should not be permitted, particularly if the effect is to diminish or impair the development of a co-channel system which already has qualified for exclusivity in the same area. MAP replies that it is not asking to expand the rights of grandfathered licensees, but only is seeking a clarification of the types of "minor" modifications that the FCC will allow. MAP does not want the rules interpreted in a manner that hampers the ability of existing licensees to improve service, respond to customer needs, and adjust to business changes.

**Decision.** The rules provide that grandfathered licensees who do not qualify for exclusivity may make modifications to existing facilities that do not impair the exclusivity rights of co-channel licensees or otherwise violate our rules. There is no reason to change this rule, based on MAP's petition. This issue is raised more broadly in the *Notice of Proposed Rule Making* in WT Docket No. 96-18. Therefore, the Commission will defer additional consideration of the issues raised by MAP to that proceeding.

#### G. Miscellaneous

In the *PCP Exclusivity Order*, the Commission addressed the issue of conditional operation of 929-930 MHz stations located above "Line A," i.e., within 250 miles of the Canadian border. Noting that a 1992 agreement between the Commission and Canada's Department of Communications had eliminated the need for international coordination of these channels, the Commission stated that it would allow operation of 929 MHz stations above Line A, provided all other requirements of the rules are met. Some licensees have misconstrued this language in the *PCP Exclusivity Order* to open all channels in the 929-930 MHz band to operation by U.S. licensees above Line A. In fact, the 1992 U.S.-Canada agreement provides that only channels between 929.5 and 930 MHz may be used by U.S. licensees above Line A. To eliminate any possible confusion, the Commission clarifies that operation above Line A (which is now within 75 miles of the Canadian border) is allowed only on these channels. In accordance with the 1992 agreement, no U.S. licensee may operate conditionally or otherwise on channels from 929.0 MHz to 929.5 MHz.

#### IV. Conclusion

The Commission is amending the rules as described above to facilitate the rapid and efficient licensing of paging in the 929-930 MHz band. The limited



amendments to the regional channel exclusivity scheme established in the *PCP Exclusivity Order* will facilitate the development of seamless, wide-area 900 MHz paging systems. Otherwise, the Commission affirms the rules as adopted in the *PCP Exclusivity Order*.

#### V. Procedural Information

##### Regulatory Flexibility Analysis

Pursuant to the Regulatory Flexibility Act of 1980, the Commission's final analysis is as follows:

##### A. Need for and Purpose of This Action

This *Memorandum Opinion and Order* makes amendments to Part 90 of the Commission's rules relating to channel exclusivity for qualified local, regional, and nationwide private paging systems on certain channels at 929–930 MHz. The amendments will promote the efficient use of paging channels by encouraging investment in new paging technology. They also will foster the development of more efficient paging systems on a local, regional, and nationwide basis.

##### B. Summary of Issues Raised by Public Comments in Response to the Initial Regulatory Flexibility Analysis

Only one party, Radiofone, filed comments responding to the Initial Regulatory Flexibility Analysis (IRFA). Radiofone argued that the Commission has not adequately addressed the impact of the proposal on small paging systems and that exclusive licensing will preclude small business entry at 900 MHz. The Commission reviewed Radiofone's concerns in the context of *PCP Exclusivity Order*. No additional comments have been submitted.

##### C. Significant Alternatives Considered and Rejected

As the Commission determined in the *PCP Exclusivity Order* and affirms in this *Memorandum Opinion and Order*, this action is fully consistent with the Commission's small business policy objectives. The Commission noted in the IRFA that this action imposes certain conditions on the licensing of smaller 929–930 MHz paging systems, but these requirements are not unduly burdensome. The new rules contain significant benefits for small businesses by protecting dozens of small existing systems in place, allowing many such systems to obtain exclusivity, and creating opportunities for expansion and new entry by small business licensees.

##### Ordering Clauses

It is ordered that pursuant to the authority of Sections 4(i), 303(g) 303(r),

and 332(a) of the Communications Act of 1934, as amended, 47 U.S.C. §§ 154(i), 303(g), 303(r) and 332(a), 47 CFR Part 90, is amended as set forth below, effective April 4, 1996.

It is further ordered that the petitions for reconsideration filed by National Association of Business and Educational Radio/ Association for Private Carrier Paging Section, First National Paging Company, Inc., Afro-American Paging, American Mobilephone, Inc., Paging Network, Inc., MAP Mobile Communications, Inc. and Metrocall, Inc. are granted to the extent described above and are denied in all other respects.

It is further ordered that the waiver requests filed by American Mobilephone, Inc., Arch Communications Group, Inc., Comtech, Inc., First National Paging Company, Inc., Message Center Beepers, Inc., Metrocall, Inc. and PacTel Paging (now "Airtouch Paging") are granted to the extent described above.

It is further ordered that, pursuant to the authority of Section 0.331 of the Communications Act of 1934, as amended, we delegate to the Wireless Telecommunications Bureau the authority to address any request for waiver of our exclusivity rules, which shall be evaluated based on criteria set forth above.

It is further ordered that this proceeding is terminated.

##### List of Subjects in 47 CFR Part 90

Common carriers.

Federal Communications Commission.  
William F. Caton,  
*Acting Secretary*.

##### Rule Amendments

Part 90 of Chapter I of Title 47 of the Code of Federal Regulations is amended as follows:

#### PART 90—PRIVATE LAND MOBILE RADIO SERVICES

1. The authority citation for Part 90 continues to read as follows:

Authority: Sections 4, 303, 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 303, and 332, unless otherwise noted.

2. Section 90.494 is amended by revising paragraph (g) to read as follows:

##### **§ 90.494 One-way paging operations in the 929–930 MHz band.**

\* \* \* \* \*

(g) Stations operating as part of regional or local systems under § 90.495(a)(1) or (a)(2) may also operate sites within their existing service area at a maximum effective radiated power of 3500 watts, provided that such an

increase in power does not expand the licensee's service-area contour, and the requirements of § 90.495(b)(2) are met as to any co-channel system that has preexisting exclusivity rights.

[FR Doc. 96–4723 Filed 3–4–96; 8:45 am]

BILLING CODE 6712–01–P

#### DEPARTMENT OF COMMERCE

##### National Oceanic and Atmospheric Administration

##### 50 CFR Part 380

[Docket No. 950707173–6036–02; I.D. 012296E]

RIN 0648–AF51

##### Antarctic Marine Living Resources Convention Act of 1984; Conservation and Management Measures

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Final rule.

**SUMMARY:** The Secretary of Commerce (Secretary) amends the regulations governing harvesting and reporting of Antarctic living marine resource catches by vessels of, and persons subject to the jurisdiction of, the United States. The regulations implement conservation and management measures implemented by the Commission for the Conservation of Antarctic Marine Living Resources (CCAMLR or Commission) and accepted in whole by the Government of the United States to regulate catches in Convention for the Conservation of Antarctic Marine Living Resources (Convention) statistical reporting areas 48 and 58. These measures restrict the use of gear, restrict the directed taking and bycatch of certain species of fish, prohibit the taking of other species, and require real-time and other reporting of the harvest of certain species.

**EFFECTIVE DATE:** February 29, 1996.

**ADDRESSES:** A copy of the framework environmental assessment may be obtained from the Assistant Administrator for Fisheries, NOAA, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910.

Comments regarding burden estimates or collection of information aspects of this rule should be sent to Robin Tuttle, (See **ADDRESSES**), and to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, D.C. 20503, Attention: NOAA Desk Officer.

**FOR FURTHER INFORMATION CONTACT:**  
Robin Tuttle, NMFS International  
Organizations and Agreements Division,  
301-713-2282.

**SUPPLEMENTARY INFORMATION:**

**Background**

At its annual meeting in Hobart, Tasmania, in 1986, CCAMLR, of which the United States is a member, adopted a conservation measure requiring the Commission at subsequent meetings to adopt limitations on catch, or to implement equivalent measures, which would be binding for species upon which fisheries are permitted in Convention subarea 48.3 (South Georgia), depicted at (Figure 1 to part 380). The Commission has, also, adopted measures that apply to other Convention subareas.

The measures adopted at the 1995 meeting of the Commission address the 1995-96 and 1996-97 fishing seasons. The measures are based upon the advice of the Scientific Committee and take into account research conducted by Commission members and the reports and recommendations of the Scientific Committee's working groups. The 1995-96 fishing season is defined as the period from November 4, 1995, to the end of the Commission meeting in 1996 (November 1, 1996). The 1996-97 fishing season is defined as the period from the end of the Commission meeting in 1996 (November 1, 1996) to the end of the Commission meeting in 1997 (likely October 31, 1997). The 1997-98 fishing season is not defined, but will likely run for the period from October 31, 1997 to the end of the Commission meeting in 1998. There are shorter fishing periods defined for specific fisheries.

**Comments and Responses**

The measures were announced and public comments invited (until January 9, 1996) by a Federal Register notice on December 12, 1995 (60 FR 63752). Comments supporting the measures were received from the Pacific Seabird Group (PSG) and H.T. Harvey & Associates (Harvey).

PSG suggested that longline gear be modified to release hooks and longlines underwater. Department of State (DOS) noted that the United States tabled a paper at the 1995 CCAMLR meeting on the potential for longline systems which release baited line underwater. The paper was strongly supported and CCAMLR requested that Members using such systems report to the Scientific Committee on their effectiveness in eliminating seabird bycatch.

PSG recommended that CCAMLR study whether the number of seabirds

attracted to longline sets would decrease if the dumping of offal were reduced. DOS noted that CCAMLR has prohibited the discharge of offal during setting or hauling on the side of the vessel on which longlines are set or hauled.

PSG also suggested that CCAMLR study measures to decrease the effects of longlines on nocturnal foragers, like petrels, that become entangled and die when nets are set at night. DOS reported that CCAMLR has recognized the urgent need for research into ways of reducing the bycatch of white-chinned petrels, especially at night, and has called for further work on relationships between hook size and the bycatch of petrels.

PSG urged that longline fishery measures be enforced, and their effects monitored and made public. DOS noted that in the *Dissostichus eleginoides* (Patagonian toothfish) fishery in subarea 48.3, the primary fishery in which seabird mortality has been a problem, all vessels are required by CCAMLR to have at least one scientific observer, appointed in accordance with the CCAMLR Scheme of International Scientific Observation, aboard throughout all fishing activities within the fishing period.

With respect to the krill fishery, PSG recommended that CCAMLR scientists continue to monitor the fishery to determine whether the current precautionary limit is appropriate. DOS noted that the United States has concerns about the proposed use of a new krill productivity model and will ensure that the lower existing krill catch rate is maintained until the integrity of the newer model can be assured.

Both PSG and Harvey recommended a study of the importance of *Electrona carlsbergi* (lanternfish) to the Scotia Sea ecosystem and foodwebs. DOS indicated that it will forward the suggestion to the interagency group involved in preparations for the 1996 meeting of CCAMLR.

**A. Changes in Taxonomy**

The Commission recognized changes in taxonomy for *Notothenia squamifrons* (grey rockcod), now called *Lepidorhynchus squamifrons*, and *Notothenia gibberifrons* (humped rockcod), now called *Gobionotothen gibberifrons*.

**B. Data Reporting Requirements**

The Commission has, at past annual meetings, adopted detailed, fine-scale reporting requirements. These measures continue in force until amended or revoked. The Commission reduced the overall reporting burden for the 1995-96 fishing season.

The Commission reopened the fishery for *Champscephalus gunnari* (mackerel icefish) in statistical area 48.3 and required the use of: (1) CCAMLR Form C1 to report haul-by-haul data finescale catch and effort for trawl fisheries, and (2) CCAMLR Form B2 to report length composition measurements. The forms must be submitted at the end of each month of fishing. This reporting is a lesser level of reporting than in 1993-94, when the fishery was last open and during which fishers were also required to report catch and effort on a 5-day basis.

The Commission modified the data requirements for the exploratory crab fishery in statistical subarea 48.3 by requiring a count of and estimated weight total for *D. eleginoides* and *Notothenia rossii* (marbled rockcod) and estimated total weight of other species taken as bycatch. The regulations impose this additional requirement, but remove past requirements for a Commercial Vessel Daily Activity Logbook; a Commercial Vessel Fishing Effort Logbook; and a Commercial Vessel CCAMLR Subsample Logbook. The data reporting required by the experimental harvest regime (adopted by the Commission in 1993 and included in previous regulations) serves the purpose of those logbook requirements.

The Commission identified the bycatch species (any cephalopod, crustacean or fish species other than *E. carlsbergi*) to which the continuing requirement for monthly biological data reporting for *E. carlsbergi* in statistical subarea 48.3 applies. The regulations note these species.

The Commission required the use of the existing systems of every 10-day catch and effort reporting and monthly effort and biological data reporting to report data from the new fisheries for *D. eleginoides* and *Dissostichus mawsoni* (Antarctic toothfish) in statistical division 58.4.3 and deep-water species in statistical division 58.5.2. However, since these bottom-trawling only fisheries are limited to Australian vessels, the data reporting requirements are not included in the regulations.

The Commission made reporting for *C. gunnari* and *D. eleginoides* in statistical subarea 58.5.2 less burdensome, by reducing the frequency of required catch and effort reporting from every 5 days to every 10 days.

**C. Longline Fishing**

The Commission further defined the actions which fishers must take while longline fishing or conducting longline fishing research in the Convention Area in order to minimize the incidental

mortality of seabirds. The regulations are amended to permit longline fishing consistent with Commission restrictions.

#### D. Finfishing in Subareas 48.1 (South Shetlands Islands)

The Commission continued prohibitions on the taking of all species of finfish, other than for scientific research purposes, in subareas 48.1 and 48.2 from November 6, 1993, until at least such time that a survey of stock biomass is carried out, and a decision that the fishery is to be reopened is made by the Commission based on the advice of the Scientific Committee.

#### E. Finfishing in Subarea 48.3 (South Georgia)

The Commission took action on finfishing in subarea 48.3 for the 1995–96, 1996–97, and 1997–98 fishing seasons, as follows:

The prohibition on directed fishing for *G. gibberifrons*, *Chaenocephalus aceratus* (blackfin icefish), *Pseudochaenichthys georgianus* (South Georgia icefish), *L. squamifrons*, and *Patagonotothen brevicauda guntheri* (Patagonian rockcod) for the 1994–95 and 1995–96 fishing seasons is continued.

In any directed fishery in the subarea, in any fishing season, the bycatch limit for *G. gibberifrons* is 1,470 metric tons (mt); the bycatch limit for *C. aceratus* is 2,200 mt; and the bycatch limit for *P. georgianus*, *N. rossii*, and *L. squamifrons* is 300 mt each, the 1992–93 levels. This measure was previously given seasonal application.

The total allowable catch (TAC) for *E. carlsbergi* is reduced. The TAC for the 1995–96 fishing season is 109,000 mt. In addition, the TAC for *E. carlsbergi* is 14,500 mt in the Shag Rocks region. The directed fishery for *E. carlsbergi* will close if a bycatch limit set for *G. gibberifrons*, *C. aceratus*, *P. georgianus*, *N. rossii*, or *L. squamifrons* is reached for any of these species or if the TAC for *E. carlsbergi* reaches 109,000 mt, whichever comes first.

The directed fishery for *E. carlsbergi* in the Shag Rocks region will close if a bycatch limit for any of the bycatch species is reached, or if the TAC of 14,500 mt is reached, whichever comes first. If, in the course of the directed fishery for *E. carlsbergi*, the bycatch of any one haul of the bycatch species exceeds 5 percent, the fishing vessel must move to another fishing location within the subarea. This location was not defined for the 1994–95 season. For the 1995–96 season, it is defined as a fishing location not closer than 5 nautical miles (9.26 km) distant. The

fishing vessel must not fish for at least 5 days within 5 nautical miles (9.26 km) of the location in which the catch of species, other than the target species, exceeded 5 percent. The relocation distance and the use of a 5-day waiting period were adopted pending the adoption of a more appropriate distance and period.

The TAC of *D. eleginoides* was increased to 4,000 mt for a fishing season defined from March 1, 1996, to August 31, 1996, or until the TAC is reached, whichever comes first. Each vessel participating in the fishery must carry at least one scientific observer, appointed in accordance with the CCAMLR Scheme of International Scientific Observation, aboard throughout all fishing activities within the fishing period. Directed fishing must be by longlines only. Submission of catch and effort data continue to be required on an every-5-day reporting basis. The monthly reporting of representative samples of length composition measurements using forms provided by the Scientific Committee continues to be required during the 1995–96 fishing season. Failure by any Contracting Party, including the United States, to submit length composition data for three consecutive reporting periods will result in the closure of the fishery to the vessels of the Contracting Party.

The fishery for *C. gunnari* was reopened with a TAC of 1,000 mt. The directed fishery for *C. gunnari* will close when the bycatch limit for any designated bycatch species is reached. If, in the course of the directed fishery, the bycatch of any one haul of a designated bycatch species exceeds 5 percent, the fishing vessel must move to another location not closer than 5 nautical miles (9.26 km) distant. For at least 5 days, the fishing vessel must fish within 5 nautical miles (9.26 km) of the location in which the bycatch exceeded 5 percent. Vessels must undertake a scientific survey carried out in accordance with a survey design specified in the CCAMLR Draft Manual for Bottom Trawl Surveys in the Convention Area. Each vessel must have a scientific observer, appointed in accordance with the CCAMLR Scheme of International Scientific Observation, aboard throughout all fishing activities within the fishing season.

#### F. Finfishing in Subarea 48.4 (South Sandwich Islands)

The TAC for *D. eleginoides* in subarea 48.4 is 28 mt for the 1995–96 fishing season beginning March 1, 1996, and ending on the earliest of August 31, 1996; reaching the TAC for *D.*

*eleginoides* in subarea 48.3; or reaching the TAC for *D. eleginoides* in subarea 48.4. Each vessel participating in the fishery must carry at least one scientific observer, appointed in accordance with the CCAMLR Scheme of International Scientific Observation, aboard throughout all fishing activities within the fishing period.

Every 5-day catch and effort data and monthly reporting of representative samples of length composition measurements using forms provided by the Scientific Committee continue to be required.

#### G. Finfishing in Division 58.4.3

Finfishing for *Dissostichus* species in statistical division 58.4.3 for the 1995–96 fishing season is closed to all but Australian vessels.

#### H. Finfishing in Division 58.4.4 (Ob and Lena Banks)

Measures adopted in 1992 setting TACs for the 1993–94 fishing season were continued at the 1994 meeting for the 1994–95 and 1995–96 fishing seasons. The TAC for *L. squamifrons* for the 2-year period is 1,150 mt with 715 mt allocated to Lena Bank and 435 mt allocated to Ob Bank. Each vessel participating in the fishery in 1994–95 and 1995–96 must carry at least one scientific observer, appointed in accordance with the CCAMLR Scheme of International Scientific Observation, aboard throughout all fishing activities within the fishing period.

#### I. Finfishing in Division 58.5.32 (McDonald and Heard Islands)

In 1994, the Commission adopted a measure of continuing application setting precautionary catch limits in division 58.5.2 of 311 mt for *C. gunnari* and 297 mt (by trawling only) for *D. eleginoides*. The monthly effort and biological data reporting requirement established previously for other fisheries continues to apply, but the 5-day reporting of catch and effort has been reduced to 10-day reporting.

Fishing seasons commence in each year at the close of the annual meeting of the Commission and continue until the earlier of June 30 or reaching the precautionary catch limits.

If in the course of a directed fishery for *D. eleginoides* or *C. gunnari*, the bycatch in any haul of the species *L. squamifrons*, *N. rossii*, *Channichthys rhinerratus* (unicorn icefish) of *Bathyrhaja* spp. (Antarctic rays) exceeds 5 percent, the fishing vessel must move to another fishing location not closer than 5 nautical miles (9.26 km) distant. For a period of at least 5 days, the fishing vessel must not fish within 5 nautical

miles (9.26 km) of the location in which the bycatch exceeded 5 percent. The relocation distance and the use of a 5-day waiting period were adopted pending the adoption of a more appropriate distance and period.

In statistical division 58.5.2, fishing for deep-water species other than *D. eleginoides* is closed to all but Australian vessels for the 1995–96 fishing season.

#### J. Fishing for *Euphausia superba* (Antarctic Krill)

Measures adopted by the Commission at its 1991 and 1992 meetings capping the catch of krill at 1.5 million mt in area 48 in any season continues in force. The cap in subarea 58.4.2 was raised to 450,000 mt during any fishing season.

#### K. Fishing for Antarctic Crab

The Commission continued measures adopted in 1992 limiting the exploratory crab fishery in subarea 48.3 and specifying data requirements through the 1995–96 fishing season. The crab fishery continues to be limited to a TAC of 1,600 mt and to one vessel per Commission Member.

An experimental harvest regime (EHR) adopted in 1993 was extended through the 1997–98 fishing season. Vessels conducting Phase 2 of the EHR are no longer required to fish within squares as defined by specific longitude and latitude. Fishing during Phase 2 requires that vessels fish in 3 squares measuring approximately 26 square nautical miles (48.15 square km) in an area and with overall dimensions of 6° lat by 7.5° long. Vessel captains determine the location of the 3 squares to be fished, but the squares selected must be contiguous and the distance between the boundaries of any 2 squares must be at least 4 nautical miles (7.41 km). This will allow vessels to fish in preferred depth ranges.

The soak time for each string of crab pots is defined as the time between the start of setting and the start of hauling.

#### Classification

NMFS has determined that this rule is necessary to implement the Antarctic Marine Living Resources Convention Act of 1984 (the Act) and to give effect to the management measures adopted by CCAMLR and agreed to by the United States.

This final rule has been determined to be not significant for purposes of E.O. 12866.

It is exempt from section 553 of the Administrative Procedure Act, because it involves a foreign affairs function of the United States.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB Control Number.

This rule contains a collection-of-information requirement subject to the Paperwork Reduction Act. The collection of information has been approved by OMB under OMB Control Number 648–0194, which expires August 31, 1997. The annual reporting burden for this collection of information is estimated to average 44½ hours in harvesting and import permit-related activities; 1½ hours in CCAMLR Ecosystem Monitoring Program permit-related activities; ½ hour for finfish reporting in the crab fishery; 6½ hours for crab data reporting; 1 hour of radio contact; and ½ hour for reporting biological data in the finfish and crab fisheries. The response estimates shown include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Robin Tuttle, NMFS, and to the Office of Information and Regulatory Affairs (see ADDRESSES).

#### List of Subjects in 50 CFR Part 380

Administrative practice and procedure, Antarctica, Fish, Imports, Marine resources, Reporting and recordkeeping requirements, Treaties, Wildlife.

Dated: February 23, 1996.

Gary Matlock,

Program Management Officer, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 380 is amended as follows:

#### PART 380—ANTARCTIC MARINE LIVING RESOURCES CONVENTION ACT OF 1984

1. The authority citation for part 380 continues to read as follows:

Authority: 16 U.S.C. 2431 *et seq.*

#### § 380.2 [Amended]

2. In § 380.2, the definition of “fishing season” is removed, and in the definition for “Antarctic finfishes”, in the table, the entries in the left column *Notothernia gibberifrons* and *Notothernia squamifrons* are removed and the

entries *Gobionotothen gibberifrons* and *Lepidorhirus squamifrons* are added in their place, respectively.

3. In § 380.23, paragraphs (b)(1), (c) through (j), paragraphs (k) introductory text, (k)(5)(v)(A), (k)(5)(ix), and (k)(5)(xiii) are revised and paragraphs (k)(5)(ii)(G) and (l) through (n) are added to read as follows:

#### § 380.23 Catch restrictions.

\* \* \* \* \*

(b) \* \* \*

(1) The total catch of *E. superba* shall not exceed 450,000 mt in any fishing season.

\* \* \* \* \*

(c) The following catch restrictions apply to *D. eleginoides* in statistical subarea 48.4 (Figure 1 to part 380):

(1) The total catch of *D. eleginoides* shall not exceed 28 mt.

(2) For the purposes of applying this catch restriction, the fishing season begins on March 1, 1996, and ends on August 31, 1996.

(3) Each vessel participating in the fishery must carry at least one scientific observer, appointed in accordance with the CCAMLR Scheme of International Scientific Observation, aboard throughout all fishing activities within the fishing period.

(d) The following directed fishing is prohibited in statistical subarea 48.3 (Figure 1 to part 380):

(1) Directed fishing on *N. rossii*.

(2) Directed fishing on *G. gibberifrons*, *C. aceratus*, *P. georgianus*, *L. squamifrons*, and *P.b. guntheri* from November 5, 1994, through November 1, 1996.

(e) The following bycatch limitations apply in statistical subarea 48.3 during any fishing season:

(1) The bycatch of *G. gibberifrons* shall not exceed 1,470 mt.

(2) The bycatch of *C. aceratus* shall not exceed 2,200 mt.

(3) The bycatch of *P. georgianus*, *N. rossii*, and *L. squamifrons* shall not exceed 300 mt each.

(f) The following catch restrictions apply to *D. eleginoides* in statistical subarea 48.3 from March 1, 1996, through August 31, 1996, or until the total allowable catch is reached, whichever comes first:

(1) The total catch of *D. eleginoides* shall not exceed 4,000 mt.

(2) Each vessel participating in the fishery must carry at least one scientific observer, appointed in accordance with the CCAMLR Scheme of International Scientific Observation, aboard throughout all fishing activities within the fishing period.

(g) The following catch restrictions apply to *E. carlsbergi* in statistical

subarea 48.3 from November 3, 1995, through November 1, 1996:

(1) The total catch of *E. carlsbergi* shall not exceed 109,000 mt.

(2) The total catch of *E. carlsbergi* shall not exceed 14,500 mt in the Shag Rocks region, defined as the area bounded by 52°30' S. lat., 40° W. long.; 52°30' S. lat., 44° W. long.; 54°30' S. lat., 40° W. long.; and 54°30' S. lat., 44° W. long..

(3) If in the course of the directed fishery for *E. carlsbergi*, the bycatch in any one haul exceeds 5 percent of any bycatch species in paragraph (e), the fishing vessel must move to another fishing location within the subarea not closer than 5 nautical miles (9.26 km), for a period of at least 5 days.

(h) The taking of finfish, other than for scientific research purposes, is prohibited in subareas 48.1 and 48.2 (Figure 1 to part 380).

(i) The following catch restrictions apply to *L. squamifrons* in statistical division 58.4.4 (Figure 1 to part 380) from November 5, 1994, through November 1, 1996:

(1) The total catch of *L. squamifrons* for this period shall not exceed 715 m on Lena Bank and 435 mt on Ob Bank.

(2) Each vessel participating in the fishery shall carry a scientific observer, appointed in accordance with the CCAMLR scheme of International Scientific Observation aboard throughout all fishing activities within the fishing period.

(j) The following catch restrictions apply to statistical division 58.5.2 (Figure 1 to part 380) for each fishing season. (For purposes of applying this limit, a fishing season begins at the close of the annual meeting of CCAMLR and continues until the earlier of June 30 or until respective precautionary catch limits are reached, whichever comes first):

(1) The total catch limit for *C. gunnari* is 311 mt.

(2) The total catch limit for *D. eleginoides* is 297 mt.

(3) If in the course of a directed fishery for *C. gunnari* or *D. eleginoides*, the bycatch in any haul exceeds 5 percent for *L. squamifrons*, *N. rossii*, *C. rhinoceros* or *Bathyrja spp.*, the fishing vessel shall move to another location not closer than 5 nautical miles (9.26 km) distant. For a period of at least 5 days, the fishing vessel shall not fish within 5 nautical miles (9.26 km) of the location in which the bycatch exceeded 5 percent.

(k) The following catch restrictions apply to fishing for any Antarctic crab species in the crab group Order Decapoda, Suborder Reptantia, in

statistical area 48 from November 4, 1995, through November 1, 1996:

\* \* \* \* \*

(5) \* \* \*

(ii) \* \* \*

(G) Soak time is defined for each string of crab pots as the time between the start of setting and the start of hauling.

\* \* \* \* \*

(v) \* \* \*

(A) Every vessel conducting Phase 2 shall fish in 3 small squares measuring approximately 26 nautical miles (48.15 km) in area (the dimension of these squares shall be 6.0° lat. by 7.5° long. The squares shall be subdivisions of the blocks delineated in Phase 1 of the experimental regime. Vessel captain shall determine the location of the 3 squares that will be fished, but selected squares may not be contiguous and the distance between the boundaries of any 2 squares must be at least 4 nautical miles (7.41 km).

\* \* \* \* \*

(ix) Data collected during the experimental harvest regime up to June 30 in any split-year shall be submitted to the CCAMLR Data manager by August 31 of the following split year.

\* \* \* \* \*

(xiii) The experimental regime shall be instituted for a period of 3 split-years (1995–96 to 1997–98). Fishing vessels that begin experimental fishing in the 1997–98 split-year must complete the regime during the 1998–99 split-year.

(l) The following catch restrictions apply to *C. gunnari* in statistical subarea 48.3 from November 3, 1995, through March 31, 1996:

(1) The total catch of *C. gunnari* shall not exceed 1,000 mt.

(2) The fishery shall close if the bycatch of any of the species listed in paragraph (e) above reaches its bycatch limit or if the total catch of *C. gunnari* reaches 1,000 mt, whichever comes first.

(3) If, in the course of the directed fishery for *C. gunnari*, the bycatch in any one haul exceeds 5 percent for any of the species listed in paragraph (e) of this section, the fishing vessel shall move to another location not closer than 5 nautical miles (9.26 km) distant. For a period of at least 5 days, the fishing vessel shall not fish within 5 nautical miles (9.26 km) of the location in which the bycatch exceeded 5 percent.

(4) Each vessel participating in the directed fishery for *C. gunnari* is required to undertake a scientific survey carried out in accordance with the survey design specified in the CCAMLR Draft Manual for Bottom Trawl Surveys in the Convention Area.

(5) Each vessel participating in the directed fishery for *C. gunnari* shall

have a scientific observer, appointed in accordance with the CCAMLR Scheme of International Scientific Observation, aboard throughout all fishing activities within the fishing season.

(m) Vessels of, and persons subject to the jurisdiction of, the United States shall not fish for *D. eleginoides* and *D. mawsoni* in statistical 58.4.3 from November 4, 1995, through June 30, 1996.

(n) Vessels of, and persons subject to the jurisdiction of, the United States shall not fish for deep-water species other than *D. eleginoides* and *C. gunnari* in statistical division 58.5.2 from November 4, 1995, through June 30, 1996.

4. In § 380.24, the introductory text to paragraphs (a) through (d) are revised, paragraph (e) is removed, paragraphs (f) and (g) are redesignated as paragraphs (e) and (f) respectively, the introductory text to redesignated paragraphs (e), (f), (f)(1), and redesignated paragraphs (f)(2) and (f)(3) are revised, and paragraphs (e)(4), (e)(5) and (f)(4) are added to read as follows:

#### § 380.24 Reporting requirements.

(a) Five-day catch and effort reporting is established for catches in the Convention Area greater than 5 mt taken during fishing for research purposes; for *D. eleginoides* in statistical subareas 48.3 and 48.4; and for *L. squamifrons* in statistical division 58.4.4 as follows:

\* \* \* \* \*

(b) Ten-day catch and effort reporting is established for fishing for any member of the crab group (Order Decapoda, Suborder Reptantia) in statistical area 48; *C. gunnari* in statistical division 58.5.2; and *D. eleginoides* in statistical division 58.5.2 as follows:

\* \* \* \* \*

(c) Monthly catch and effort reporting is established for *E. superba* in statistical area 48 and in statistical subdivision 58.4.2; and for *E. carlsbergi* in statistical subarea 48.3 as follows:

\* \* \* \* \*

(d) Monthly effort and biological data reporting for trawl fisheries is established for *E. carlsbergi* in statistical subarea 48.3; for the bycatch of any cephalopod, crustacean or fish species other than *E. carlsbergi* in the directed fishery for *E. carlsbergi* in statistical area 48.3; for *L. squamifrons* in statistical division 58.4.4; for the bycatch of *D. eleginoides* in the directed fishery for *L. squamifrons* in statistical division 58.4.4; for *C. gunnari* in statistical division 58.5.2; and for *D. eleginoides* in statistical division 58.5.2 as follows:

\* \* \* \* \*

(e) Monthly effort and biological data *D. eleginoides* for fishing in statistical subareas 48.3 and 48.4 from November 3, 1995, through November 1, 1996, is established as follows:

\* \* \* \* \*

(4) Haul-by-haul data must be reported to the Assistant Administrator For Fisheries, NOAA (AA) not later than the end of following month on the CCAMLR fine-scale catch and effort data form for longline fisheries (Form C2, latest version). These data shall include numbers of seabirds and marine mammals of each species caught and released or killed.

(5) Completed forms B2 and C2 must be conveyed by cable, telex, rapidfax, or other appropriately timely method to the number or address specified in the vessel's permit, and must include the vessel's name, permit number, month of reporting, and the catch in metric tons (to the nearest tenth of a metric ton). If no restricted species are taken during a reporting period, the operator must submit a form showing no catch or bycatch.

(f) Reporting for crab fishing (Order *Decapoda*, Suborder *Reptania*) in statistical area 48 is required as follows:

(1) The following data must be reported to the CCAMLR Data Manager by August 31, 1996 for catches taken between November 4, 1995, and July 31, 1996; by September 30, 1996 for catches taken between July 31, 1996 and August 31, 1996; and by November 17, 1996 for catches taken between August 31, 1996 and November 1, 1996:

\* \* \* \* \*

(2) Data gathered during the experimental harvest regime described in § 380.23 (k) shall be reported to CCAMLR Data Manager upon the completion of each phase of the experimental harvest.

(3) Every 10-day reporting of catch and effort data, as described in paragraph (b), is required during normal fishing between Phase 1 and Phase 2, and between Phase 2 and Phase 3 of the experimental harvest regime. Reports shall be submitted to the CCAMLR Data Manager.

(4) Copies of all data provided directly to the CCAMLR Data Manager shall be concurrently provided to the AA to the number or address specified in the vessel's permit, and must include the vessel's name, permit number, month of reporting, and catch in metric tons (to the nearest tenth of a metric ton).

5. In § 380.26, paragraphs (b) through (i) are revised to read as follows:

#### § 380.26 Closures.

\* \* \* \* \*

(b) The fishery for *D. eleginoides* in statistical subarea 48.3 shall close on August 31, 1996, or when the total catch reaches 4,000 mt, whichever comes first.

(c) The fishery for *D. eleginoides* in statistical subarea 48.4 shall close on August 31, 1996, reaching the total allowable catch for *D. eleginoides* in statistical subarea 48.3, or when the total catch reaches 28 mt, whichever comes first.

(d) The fishery for *C. gunnari* in statistical subarea 48.3 shall close on November 1, 1996, or when the total catch reaches 1,000 mt, whichever comes first.

(e) The directed fishery for *E. carlsbergi* in statistical subarea 48.3 shall close November 1, 1996, or when the bycatch of any of the species *G. gibberifrons*, *C. aceratus*, *N. rossii*, *L. squamifrons*, *P. georgianus*, or *P.B. guntheri* reaches its bycatch limit, or when the total catch of *E. carlsbergi* reaches 109,000 mt, whichever comes first.

(f) The directed fishery for *E. carlsbergi* in the Shag Rocks region of statistical subarea 48.3 shall close November 1, 1996, or when the bycatch of any of the species named in paragraph (e) of this section reaches its bycatch limit, or when the total catch of *E. carlsbergi* reaches 14,500 mt, whichever comes first.

(g) The fishery for *L. squamifrons* on Lena Bank in statistical division 58.4.4 shall close November 1, 1996, or when the total catch reaches 715 mt, whichever comes first.

(h) The fishery for *L. squamifrons* on Ob Bank in statistical division 58.4.4 shall close November 1, 1996, or when the total catch reaches 435 mt whichever comes first.

(i) The fishery for *C. gunnari* and *D. eleginoides* in statistical division 58.5.2 shall close the earlier of June 30 or until precautionary catch limits of 311 mt and 297 mt, respectively, are reached, whichever comes first.

6. Section 380.27 is revised to read as follows:

#### § 380.27 Gear restrictions.

(a) Longline fishing or longline fishing research in the Convention area (except for waters adjacent to the Kerguelen and Crozet Islands and the Prince Edward islands) shall be conducted as follows:

(1) Fishing operations shall be conducted in such a way that the baited hooks sink as soon as possible after they are put in the water. Only thawed bait shall be used.

(2) For vessels using the Spanish method of longline fishing, weights should be released before line tension occurs; whenever possible weights of at

least 6 kg mass should be used, spaced at 20 m intervals.

(3) Longlines shall be set only at night (between the times of nautical twilight). During longline fishing at night, only the minimum ship's lights necessary for safety shall be used. Wherever possible, setting of lines should be completed at least 3 hours before dawn (to reduce loss of bait to/catches of white-chinned petrels).

(4) The dumping of offal shall be avoided as far as possible while longlines are being set or hauled; if discharge of offal is unavoidable, the discharge must take place on the opposite side of the vessel to that where longlines are set or hauled.

(5) Every effort should be made to ensure that birds captured alive during longlining are released alive and that wherever possible hooks are removed without jeopardizing the life of the bird concerned.

(6) A streamer line designed to discourage birds from settling on baits during deployment of longlines shall be towed. Specification of the streamer line is given in Figure 2 to part 380. Details of the construction relating to the number and placement of swivels may be varied so long as the effective sea surface covered by the streamers is no less than that covered by the currently specified design. Details of the device dragged in the water in order to create tension in the line may also be varied.

(7) The streamer line is to be suspended at the stern from a point approximately 4.5 m above the water and such that the line is directly above the point where the baits hit the water.

(8) The streamer line is to be approximately 3 mm diameter, have a minimum length of 150 m and have a device at the end to create tension so that the main line streams directly behind the ship even in cross winds.

(9) At 5 m intervals commencing from the point of attachment to the ship five branch streamers each comprising two strands of approximately 3 mm cord should be attached. The length of the streamer should range between approximately 3.5 m nearest the ship to approximately 1.25 m for the fifth streamer. When the streamer line is deployed the branch streamers should reach the sea surface and periodically dip into it as the ship heaves. Swivels should be placed in the streamer line at the towing point, before and after the point of attachment of each branch streamer and immediately before any weight placed at the end of the streamer line. Each branch streamer should also have a swivel at its attachment to the streamer line.

(10) Variations in the design of the streamer lines may be tested on vessels carrying two observers, at least one appointed in accordance with the CCAMLR Scheme of International Scientific observation, providing that all other elements of this paragraph are complied with. The streamer lines under test should be constructed and operated taking full account of principles developed by the CCAMLR Working Group on Incidental Mortality Arising from Longline fishing (WG-IMALF) and available from the AERG. Testing should be carried out independently of actual commercial fishing and in a manner consistent with § 380.30 on exploratory fisheries.

(b) The use of net monitor cables on harvesting vessels in the Convention Area (Figure 1 to part 380) is prohibited.

(c) The use of bottom trawls in the directed fishery for *C. gunnari* in statistical subarea 48.3 from November 3, 1995, through November 1, 1996, is prohibited.

(d) The use of any gear, except trawls, in the fisheries for *C. gunnari* and *D. eleginoides* in statistical subdivision 58.2.2 is prohibited.

(e) The use of any gear, except longlines, in the directed fishery for *D. eleginoides* in statistical subarea 48.3 from November 3, 1995, through November 1, 1996, is prohibited.

(f) The use of any gear, except longlines, in the directed fishery for *D.*

*eleginoides* in statistical subarea 48.4 from November 3, 1995, through November 1, 1996, is prohibited.

(g) The use of any gear, except crab pots (traps), in the crab fishery in statistical area 48 from November 3, 1995, through November 1, 1996, is prohibited.

Figure 2 [Redesignated as Appendix A to Part 380; Amended]

7. Figure 2 to part 380 is redesignated as Appendix A to part 380 and Table 2 to newly redesignated Appendix A is removed.

Figure 3 [Redesignated as Appendix B to Part 380]

8. Figure 3 to part 380 is redesignated as Appendix B to part 380 and revised to read as follows:

Appendix B to Part 380—Data Requirements for the Crab Fishery in Statistical Subarea 48.3

#### *I. Catch and Effort Data*

(1) *Cruise Descriptions*: Cruise code, vessel code, permit number, year.

(2) *Pot Descriptions*: Pot shape, dimensions, mesh size, funnel attitude, number of chambers, presence of an escape port.

(3) *Effort Descriptions*: Date, time, latitude, and longitude of the start set, compass bearing of the set, total number of pots set, spacing of pots on the line, number of pots lost depth, soak time, bait type.

(4) *Catch Descriptions*: Retained catch in numbers, bycatch of all species, incremental record number for linking with sample information.

#### *II. Data Requirements for Bycatch Species in the Exploratory Crab Fishery in Statistical Subarea 48.3*

Species	Data requirements
<i>Dissostichus eleginoides</i> .	Numbers and estimated total weight.
<i>Notothenia rossii</i>	Numbers and estimated total weight.
Other species .....	Estimated total weight.

#### *III. Biological Data*

For these data, crabs are to be sampled from the line hauled just prior to noon, by collecting the entire contents of a number of pots spaced at intervals along the line so that between 35 and 50 specimens are represented in the subsample.

(1) *Cruise Descriptions*: Cruise code, vessel code, permit number.

(2) *Sample Descriptions*: Date, position at the start of the set, line number.

(3) *Data*: Species, sex, length of at least 35 individuals, presence/absence of rhizocephalan parasites, record of the destination of the crab (kept, discarded, destroyed), record of the pot numbers from which the crab come.

9. In part 380, the words "Figure 2" and "Figure 3" are removed wherever they appear and the words "Appendix A" and "Appendix B" are added in their place, respectively.

10. A new Figure 2 is added to part 380 to read as follows:

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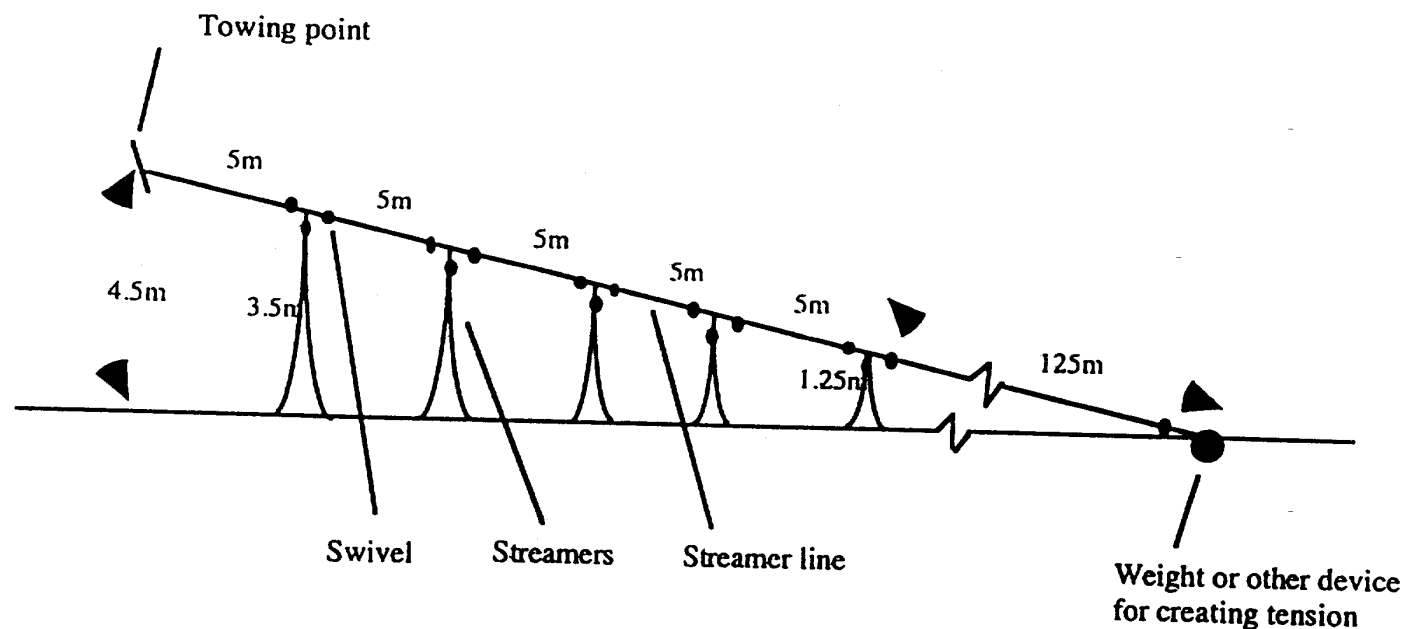


Figure 2 to Part 380—The Use of Streamer Lines to Minimize the Incidental Mortality of Seabirds in the Course of Longline Fishing or Longline Fishing Research Operations in the Convention Area (see § 380.27 for specifications on use)

[FR Doc. 96-4756 Filed 2-29-96; 3:19 pm]

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## 50 CFR Part 650

[Docket No. 9602226047-6047-01; I.D. 020696B]

RIN 0648-A137

### Atlantic Sea Scallop Fishery; Reduction in Crew Size Limit

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Final rule.

**SUMMARY:** NMFS issues this final rule to implement measures contained in Framework Adjustment 7 to the Atlantic Sea Scallop Fishery Management Plan (FMP). This framework adjustment permanently reduces the maximum crew size from nine to seven.

**EFFECTIVE DATE:** March 11, 1996.

**ADDRESSES:** Copies of Amendment 4, its regulatory impact review and the final regulatory flexibility analysis contained therein, the final supplemental environmental impact statement (SEIS), and the supporting documents for Framework Adjustment 7 are available from Douglas Marshall, Executive Director, New England Fishery Management Council, Suntaug Office Park, 5 Broadway, Saugus, MA 01906-1097.

**FOR FURTHER INFORMATION CONTACT:** Paul H. Jones, 508-281-9273.

**SUPPLEMENTARY INFORMATION:**

### Background

The final rule implementing Amendment 4 to the FMP was published on January 19, 1994 (59 FR 2777), with implementation of most measures on March 1, 1994. The amendment retained the FMP's objectives to: (1) Restore adult stock abundance and age distribution; (2) increase yield-per-recruit for each stock; (3) evaluate plan research, development, and enforcement costs; and (4) minimize adverse environmental impacts on sea scallops.

Amendment 4 changed the primary management strategy from a meat count (size) control to effort control. The amendment controls total fishing effort through limited access permits and a schedule of reductions in allowable days at sea (DAS). Supplemental measures include limits on increases in vessel fishing power to control the amount of fishing pressure and to help control the size of scallops landed, gear restrictions, and limits on the number of crew members. Additionally, the amendment includes a framework procedure for adjusting the management measures in the FMP. Initially, the maximum crew size was set at nine.

In response to very high levels of recruitment documented in the Mid-Atlantic resource area, the New England Fishery Management Council (Council) recommended lowering the maximum crew size from nine to seven, because a

smaller crew lowers shucked-scallop production. This reduced production is exacerbated if a vessel operator is targeting small scallops. Thus, this restriction provides an incentive to target larger scallops in order to obtain the same amount of yield from fewer scallops. Framework Adjustments 1 (59 FR 36720, July 19, 1994) and 4 (59 FR 36720, April 5, 1995), temporarily lowered the maximum crew size from nine to seven. The current framework adjustment 4 expires on February 29, 1996.

Because the conditions that justified lowering the maximum crew size to seven still exist, the Council recommended reducing the maximum crew-size permanently from nine to seven, until changed by plan amendment or other action.

In Framework 1, the 7-member crew limit was expected to increase yield-per-recruit, which would be realized during 1995 and 1996. No preliminary 1995 data are available to document that year's yield-per-recruit results. Yields would increase and spawning stock biomass would be greatly enhanced, but only during 1994. With an extension of the 7-member crew limit, similar results are expected as analyzed in Framework 1. Increased yield-per-recruit would occur during 1997 and 1998, and spawning stock biomass would be enhanced during 1996.

The extension of the 7-member crew limit is expected to reduce total



landings of sea scallops, resulting in an increase in ex-vessel prices in 1996. The increase in ex-vessel prices should mitigate the decrease in landings. During 1997 and 1998, landings and ex-vessel revenues are expected to increase. After 1998, the projected impact of the 7-member crew limit on ex-vessel revenues is projected to be negligible when compared with projected ex-vessel revenues associated with the 9-member crew limit.

The adjustments being made through the framework process (§ 650.40) are within the scope of analyses contained in Amendment 4 and the final SEIS. Supplemental rationale and analyses of expected biological effects, economic impacts, impacts on employment, and safety concerns are contained within the supporting documents for Framework Adjustments 1, 4, and 7 (see ADDRESSES).

The Council requests publication of the management measures as a final rule after considering the required factors stipulated in the regulations governing the sea scallop fishery (§ 650.40) and providing supporting analysis for each factor considered. The Director, Northeast Region, NMFS concurs with the Council's recommendation and has determined that Framework 7 should be published as a final rule.

NMFS is adjusting the scallop regulations following the procedure for framework adjustments established by Amendment 4 and codified in 50 CFR part 650, subpart C. The Council followed this procedure when making adjustments to the FMP, by developing and analyzing the actions over the span of a minimum of at least two Council meetings, on December 13, 1995, and January 25, 1996.

#### Comments and Responses

In accordance with the regulations, public comments on the framework adjustment were taken by the Council during its December 13, 1995, and January 25, 1996, meetings. Four members of the industry and two fishing organizations commented at the December and January meetings. The comments were in support of the recommended adjustment and urged timely implementation to avoid a hiatus when the current restriction expires.

Written comments were also received from four individuals. One comment was in favor of the 7-member crew limit and requires no response. The remaining comments and responses follow.

*Comment 1:* All commenters questioned the safety aspects of the maximum crew size.

*Response:* The analysis included in the Council's framework package suggests that, based on recent U.S. Coast Guard information (contained in a November 8, 1995, letter, with enclosure, from Captain P. J. Howard) about the scallop fishery, there is no relationship between the size of the crew and accidents aboard scallop vessels. Fishers have stated publicly that most New Bedford scallop boats carried less than seven crew members in the winter of 1994-95, simply because scallop stocks were low. Many fishers have also stated that there is nothing inherently dangerous about using a 7-person crew and that safety ultimately depends upon on-board safety practices rather than crew size. The Coast Guard reported to the Council in the above-mentioned November 8 letter and enclosure that there was no statistical evidence that the number of personnel casualties has increased due to the maximum crew restrictions.

*Comment 2:* The 7-person crew limit discriminates against those who have larger, more expensive vessels. Crew size limits, if required, should be based on horsepower, vessel length, tonnage, and size of gear fished.

*Response:* The Council's policy is to treat all vessels, within the full-time, part-time, and occasional categories, equally. The 7-person crew limit is based on the typical full-time vessel, which generally includes the largest, most expensive vessels and is intended to reduce the incentive to target small scallops. Although there may be smaller, less expensive vessels in the full-time category that already use 7-person crews, or less, it is unlikely due to their limited crew that these vessels pursue small scallops.

*Comment 3:* Wheelhouses are unmanned during haulbacks because of the 7-person crew limit.

*Response:* Members of the Council's Sea Scallop Industry Advisory Committee have reported that unmanned wheelhouses are a practice found regardless of crew size, in both dredges and groundfish trawls. The First Coast Guard District reported to the Council that this is a common practice among many fishing vessel operators and not unique to the scallop fishery. In any event, the decision not to man the wheelhouse is not a result of the 7-member crew limit but rather an operational decision of the captain.

#### Adherence to Framework Procedure Requirements

Neither data availability nor the need to have the 7-person crew limit in place for the entire harvesting season were factors considered by the Council in its

decision to recommend publishing the adjusted management measures as a final rule.

The public had adequate opportunity to express opinions at several meetings. The crew-limit issue was discussed at the Scallop Oversight Committee meeting held in East Boston, MA, on November 6, 1995, and at the Council meetings held in Danvers, MA, on December 13, 1995, and January 24 and 25, 1996.

There is an immediate need to protect the resource by reducing the crew limit to seven before March 11, 1996, when the current temporary crew limit expires. Unnecessary delay in effecting this adjustment would significantly increase the danger to the new incoming year-class during early spring.

The Council will continue to evaluate the effectiveness of this crew-size limit. This continuing evaluation will be made on the basis of landings data and enforcement activity.

NMFS has determined that the framework adjustment to the FMP that this rule would implement is consistent with the national standards, other provisions of the Magnuson Fishery Conservation and Management Act, and other applicable law. NMFS, in making that determination, has taken into account the information, views, and comments received during the comment period of the FMP's framework adjustment mechanism in 50 CFR 650.40.

#### Classification

This final rule has been determined to be not significant for purposes of E.O. 12866.

In that this regulation is not subject to the requirement to publish a general notice of proposed rulemaking under 5 U.S.C. 553 or any other law, this rule is exempt from the requirement to prepare an initial or final regulatory flexibility analysis under the Regulatory Flexibility Act. As such, none has been prepared.

This rule is implemented in compliance with all procedural requirements established by the Administrative Procedure Act. The Council requests publication of the management measures as a final rule after considering the required factors stipulated under the Framework Measures in the final rule for Amendment 4 and providing supporting analysis for each factor considered. Public meetings held by the Council to discuss the management measures implemented by this rule provided adequate opportunity for public comment to be considered. The Assistant Administrator (AA) for

Fisheries, NOAA, finds there is good cause to waive prior and an opportunity for public comment notice under 5 U.S.C. 553(b)(B) as such notice and public procedure thereon are unnecessary.

The AA finds that under 5 U.S.C. 553(d) the need to protect the resource by having the regulation in place by March 1, 1996, when the current temporary crew-size limit expires, constitutes good cause to waive the 30-day delay in effectiveness of this rule. Delay in effecting this crew-size limit would significantly increase the danger to the new incoming year class of sea scallops during early spring.

#### List of Subjects in 50 CFR Part 650

Fisheries, Reporting and recordkeeping requirements.

Dated: February 28, 1996.

Gary Matlock,

Program Management Officer, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 650 is amended as follows:

#### PART 650—ATLANTIC SEA SCALLOP FISHERY

1. The authority citation for part 650 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

2. In § 650.21, paragraph (c) is revised to read as follows:

##### § 650.21 Gear and crew restrictions.

(c) *Crew restrictions.* Limited access vessels participating in or subject to the scallop DAS allocation program may have no more than seven people aboard, including the operator, when not docked or moored in port, unless participating in the small dredge program specified in paragraph (e) of this section, or otherwise authorized by the Director, Alaska Region, NMFS.

\* \* \* \* \*

[FR Doc. 96-5017 Filed 2-29-96; 4:00 pm]

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#### 50 CFR Part 651

[Docket No. 960226048-6048-01; I.D. 020996A]

RIN 0648-A179

#### Northeast Multispecies Fishery

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Final rule.

**SUMMARY:** NMFS issues this final rule to implement measures contained in Framework Adjustment 14 to Amendment 5 of the Northeast Multispecies Fishery Management Plan (FMP). This rule implements a spring closure for gillnet gear in the Revised Mid-coast Closure Area and establishes a new Cape Cod South Closure Area off Southern New England. The intent of this rule is to further reduce harbor porpoise mortality in the Gulf of Maine sink gillnet fishery to meet the New England Fishery Management Council's (Council) bycatch reduction goals.

**EFFECTIVE DATES:** The addition of § 651.32(a)(1)(iv) and Figure 9 is effective March 8, 1996. The amendment to § 651.32(a)(1)(ii)(B) is effective March 25, 1996.

**ADDRESSES:** Copies of Amendment 5, its regulatory impact review (RIR) and the final regulatory flexibility analysis (FRFA) contained with the RIR, its final supplemental environmental impact statement (FSEIS), and Framework Adjustment 14 are available upon request from Douglas G. Marshall, Executive Director, New England Fishery Management Council, 5 Broadway, Saugus, MA 01906-1097.

**FOR FURTHER INFORMATION CONTACT:** E. Martin Jaffe, 508-281-9272.

#### SUPPLEMENTARY INFORMATION:

##### Background

Regulations implementing Amendment 5 to the FMP were published on March 1, 1994 (59 FR 9872). One of Amendment 5's principal objectives was to reduce the bycatch of harbor porpoise in the Gulf of Maine sink gillnet fishery by the end of Year 4 of plan implementation to a level not to exceed 2 percent of the population, based on the best available estimates of abundance and bycatch. In addition, Amendment 5 established a requirement that by September 15 of each year, the Council's Harbor Porpoise Review Team (HPRT) complete an annual review of harbor porpoise bycatch and abundance data in the Gulf of Maine and evaluate the impacts of other measures that reduce harbor porpoise take. It also encouraged the HPRT to make recommendations on other "reduction-of-take" measures to achieve the harbor porpoise mortality reduction goals and established a framework procedure for timely implementation of appropriate measures.

With the issuance of implementing regulations for Framework Adjustment 4 to Amendment 5 of the Northeast Multispecies Fishery Management Plan (59 FR 26972, May 25, 1994), a series of time and area closures to sink gillnet

gear were implemented based on an analysis by the Northeast Fisheries Science Center (NEFSC) of the seasonal and spatial distribution of harbor porpoise and sink gillnet fishing activity in the Gulf of Maine.

This action is necessary in order to make further progress toward the Council's bycatch reduction goals for Year 2 (1995-96) of the Program. The target adopted by the Council was a 40 percent reduction in the bycatch or approximately 780 animals. Due in part to the increased bycatch rates in the Mid-coast region, incidental take of harbor porpoise for that year may still exceed 1,500 animals. This information and the fact that porpoise takes had also been well documented in late March, April and May of 1995 in the Revised Mid-coast Closure Area creates a situation in which total bycatch for the 1994-95 season had likely exceeded target levels. Prior to the proposed framework adjustment, there have been no closures implemented to reduce entanglement as animals move northward into the northern Gulf of Maine and the Bay of Fundy in the spring.

This final rule implements a spring closure from March 25 through April 25 in the Revised Mid-coast Closure Area (see Figure 8), establishes an additional closure area—the Cape Cod South Closure Area—south of Massachusetts and Rhode Island (Figure 9), and implements the closure of that area from March 8 through March 30 in 1996 and from March 1 through March 30 in subsequent years. These closure areas will be monitored to determine whether displaced gillnet activity, if it occurs, results in increased harbor porpoise takes.

#### Revised Mid-coast Closure Area—Figure 8

This area is closed from March 25 through April 25 for each fishing year.

Point	Latitude	Longitude
MC1 .....	42°30' N	Massachusetts shoreline.
MC2 .....	42°30' N.	70°15' W.
MC3 .....	42°40' N.	70°15' W.
MC4 .....	42°40' N.	70°00' W.
MC5 .....	43°00' N.	70°00' W.
MC6 .....	43°00' N.	69°30' W.
MC7 .....	43°15' N.	69°30' W.
MC8 .....	43°15' N.	69°00' W.
MC9 .....	Maine shoreline	69°00' W.

#### Cape Cod South Closure Area—Figure 9

This area is closed from March 1 through March 30 of each fishing year, except in 1996 when the area is closed from March 8 through March 30.

Point	Latitude	Longitude
CCS1 .....	RI shoreline	71°45' W.
CCS2 .....	40°40' N.	71°45' W.
CCS3 .....	40°40' N.	70°30' W.
CCS4 .....	MA shoreline	70°30' W.

#### Comments and Responses

The Council has considered information, views and comments made at a meeting of its Marine Mammal Committee (MMC) held in Saugus, MA on November 28, 1995; at an informal meeting between Council staff and southern New England gillnet fishermen in Tiverton, RI on December 7, 1995; and at a full Council meeting (the first meeting for initiating the framework action) held in Danvers, MA on December 13, 1995. Documents summarizing the Council's proposed action, the biological analyses upon which this decision was based and potential economic impacts were available for public review 5 days prior to the second meeting required under the framework adjustment process. Written comments were accepted up to and at the January 25, 1996, Council meeting in Danvers, MA, at which time the decision to finalize this framework adjustment was made. Several individuals commented on the Council's proposal.

*Comment 1:* A gillnet representative requested that the Massachusetts Bay Closure Area continue to be effective from March 1 through March 30.

*Response:* The MMC proposed no change to that closure area. The Council and NMFS agree and the Massachusetts Bay Closure will remain as is, i.e., closed from March 1 through March 30.

*Comment 2:* A gillnet fisherman from Rhode Island asked that the Cape Cod South Closure Area period be from the last 2 weeks in February through the first 2 weeks in March.

*Response:* The analysis prepared by the NEFSC indicates that the harbor porpoise takes for that area are highest in March. There have been no takes observed in February.

*Comment 3:* A member of the HPRT recommended that the spring Mid-coast area closure be longer than just April.

*Response:* The MMC recommended, and the Council and NMFS agree, that effecting the Revised Mid-coast Closure Area from March 25 through April 25 will provide the maximum harbor porpoise bycatch reduction while minimizing the loss of fishing opportunity to harvesters using gillnet gear, as determined by the NEFSC analysis. The Council may seek to adjust this closure period at some future date.

*Comment 4:* A member of the HPRT recommended that the spring closure in

Massachusetts Bay be extended from February 1 through March 30. The commenter also noted that it may be necessary to extend the closures in the Mid-coast and Cape Cod South Closure Areas once additional data are available.

*Response:* The Council considered several changes to the Massachusetts Bay area closure times and determined that it had no basis for making a change. All area closures and experimental fisheries will be evaluated annually by the HPRT and recommendations for adjustments will be made as necessary.

*Comment 5:* A member of the HPRT commented that the Council action represented the best that could be done until more data become available to gauge the effectiveness of previous closures.

*Response:* The Council will consider modifying its harbor porpoise bycatch reduction goal to match the MMPA goal established under the 1994 amendments.

The Council also received several comments pertaining to an experimental fishery using small acoustic devices called pingers to deter harbor porpoise bycatch in the sink gillnet fishery. The Council forwarded these comments to the Regional Director requesting that such an experimental fishery be established in the closure areas during the closure periods. The Regional Director is considering such fisheries, which may mitigate negative economic impacts of the closures for some fishermen. The Council considered the public comments pertaining to this framework adjustment prior to making its recommendation to the Regional Director under the framework provisions for the FMP.

#### Adherence to Framework Procedure Requirements

Data were not available for a proposed rule, and the need for regulations to be in place for an entire fishing season is not an issue for this particular action. The public was provided adequate opportunity to express opinions at several meetings. These opportunities were provided at the Council's MMC held in Saugus, MA, on November 28, 1995; at an informal meeting between Council staff and southern New England gillnet fishermen in Tiverton, RI, on December 7, 1995; and at two full Council meetings held in Danvers, MA, on December 13, 1995, and January 25, 1996. There is an immediate need to provide more protection for the harbor porpoise beyond the existing management measures. There will be further evaluation of these management measures based on landings data, enforcement activity, and an expected

experimental fishery. NMFS has determined that the framework adjustment to the FMP that this rule would implement is consistent with the national standards, other provisions of the Magnuson Conservation and Management Act, and other applicable law. NMFS, in making that determination, has taken into account the information, views, and comments received during the comment period of the FMP's framework adjustment mechanism in 50 CFR 651.40.

#### Classification

In that this regulation is not subject to the requirement to publish a general notice of proposed rulemaking under 5 U.S.C. 553 or any other law, this rule is exempt from the requirement to prepare an initial or final regulatory flexibility analysis under the Regulatory Flexibility Act. As such, none has been prepared.

This final rule has been determined to be not significant for purposes of E.O. 12866.

The Assistant Administrator for Fisheries, NOAA (AA) finds there is good cause to waive prior notice and an opportunity for public comment under 5 U.S.C. 553(b)(B) as such notice and public procedure thereon are unnecessary. Public meetings held by the Council to discuss the management measures implemented by this rule provided adequate prior notice and an opportunity for public comment to be heard and considered. The AA finds that under 5 U.S.C. 553(d), the need to have the closure of the Revised Mid-coast Closure Area effective March 25 and the closure of the Cape Cod South Closure Area effective as soon as possible after March 1 while at the same time providing fishermen adequate notice to comply, to avoid delay that would likely impede the achievement of harbor porpoise mortality reduction goals, constitutes good cause to waive a portion of the 30-day delay in effectiveness of this regulation. Accordingly, the closure of the Revised Mid-coast Closure Area is effective March 25, 1996, and the closure of the Cape Cod South Closure Area is effective March 8, 1996.

#### List of Subjects in 50 CFR Part 651

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: February 28, 1996.

Gary Matlock,  
Program Management Officer, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 651 is amended as follows:

**PART 651—NORTHEAST  
MULTISPECIES FISHERY**

1. The authority citation for part 651 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

2. In §651.32 the first sentence of paragraph (a)(1)(ii)(B) is revised and paragraph (a)(1)(iv) is added to read as follows:

**§ 651.32 Sink gillnet requirements to reduce harbor porpoise takes.**

- (a) \* \* \*
- (1) \* \* \*
- (ii) \* \* \*
- (B) Notwithstanding any other provisions in this part, from March 25

through April 25 of each fishing year the restrictions and requirements specified in the introductory text of paragraph (a) of this section apply to an area known as the Revised Mid-coast Closure Area, which is an area bounded by straight lines connecting the following points in the order stated (see Figure 8 of this part). \* \* \*

(iv) *Cape Cod South Closure Area.*  
From March 6 through March 30 of fishing year 1996 and from March 1 through March 30 of subsequent fishing years, the restrictions and requirements specified in the introductory text of paragraph (a) of this section apply to an area known as the Cape Cod South

Closure Area, which is an area bounded by straight lines connecting the following points in the order stated (see Figure 9 of this part).

**CAPE COD SOUTH CLOSURE AREA**

Point	Latitude	Longitude
CCS1 .....	RI shoreline	71°45' W.
CCS2 .....	40°40' N	71°45' W.
CCS3 .....	40°40' N	70°30' W.
CCS4 .....	MA shoreline	70°30' W.

\* \* \* \* \*

3. Figure 9 is added to part 651 to read as follows:

**BILLING CODE 3510-22-W**

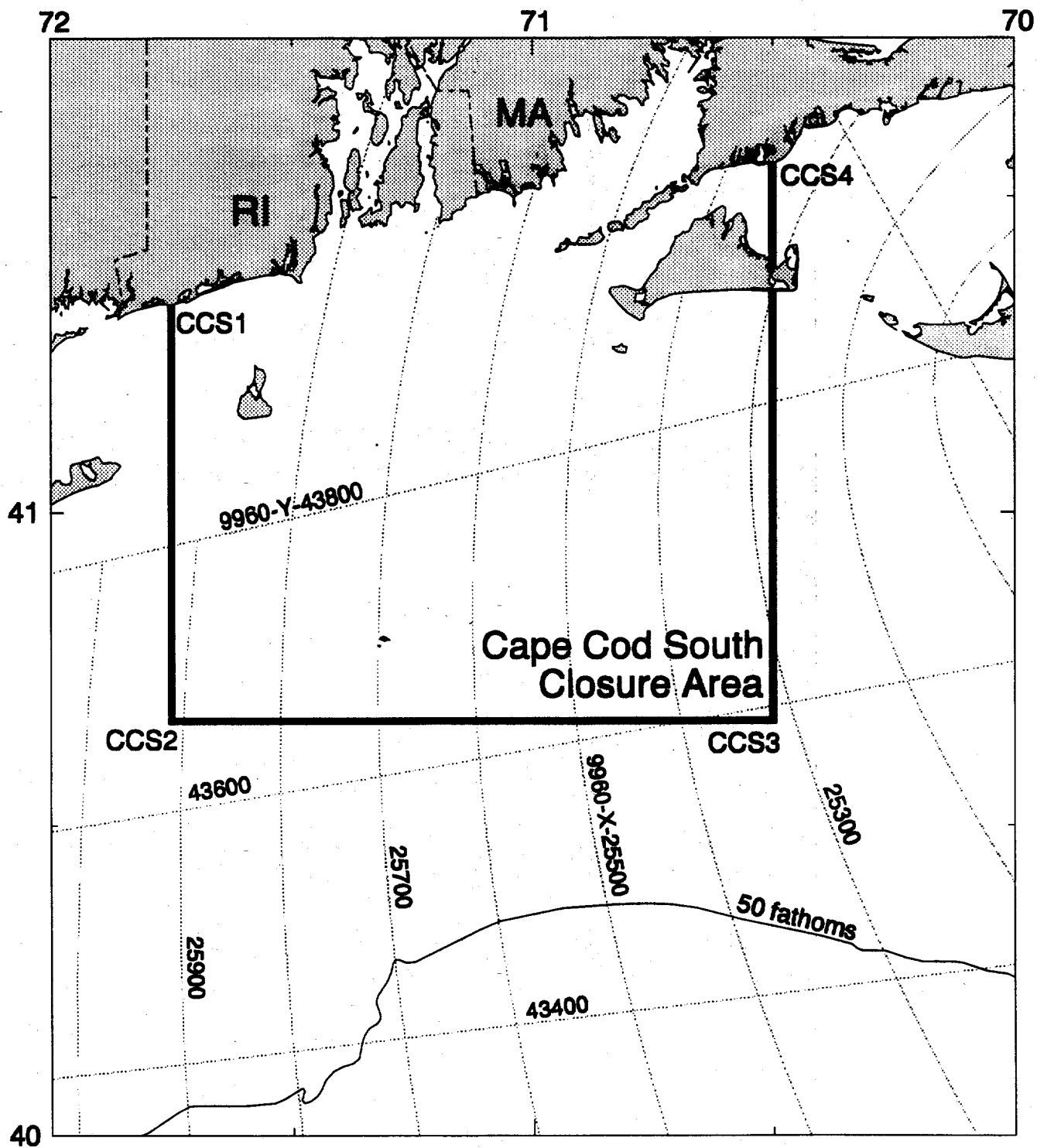


Figure 9 to Part 651—Cape Cod South Closure Area for the Protection of Harbor Porpoise

**50 CFR Part 655****[Docket No. 951211295-6035-02; I.D. 111595C]****RIN 0648-XX37****Atlantic Mackerel, Squid, and Butterfish Fisheries; Final 1996 Specifications****AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.**ACTION:** Final specifications for the 1996 Atlantic mackerel, squid, and butterfish fisheries.**SUMMARY:** NMFS issues the final initial specifications for the 1996 fishing year for Atlantic mackerel, squid, and butterfish (SMB).**EFFECTIVE DATE:** January 1, 1996, through December 31, 1996.**ADDRESSES:** Copies of the Environmental Assessment are available from the Northeast Regional Office, NMFS, 1 Blackburn Drive, Gloucester, MA 01930. Copies of the Mid-Atlantic Fishery Management Council's quota paper and recommendations are available from David R. Keifer, Executive Director, Mid-Atlantic Fishery Management Council, Room 2115, Federal Building, 300 South New Street, Dover, DE 19901.**FOR FURTHER INFORMATION CONTACT:** Myles Raizin, 508-281-9104.**SUPPLEMENTARY INFORMATION:** Regulations implementing the Fishery Management Plan for the Atlantic Mackerel, Squid, and Butterfish Fisheries (FMP) prepared by the Mid-Atlantic Fishery Management Council (Council) appear at 50 CFR part 655. These regulations require NMFS to

publish a document specifying the initial annual amounts of the initial optimum yield (IOY) as well as the amounts for allowable biological catch (ABC), domestic annual harvest (DAH), domestic annual processing (DAP), joint venture processing (JVP), and total allowable levels of foreign fishing (TALFF) for the species managed under the FMP. No reserves are permitted under the FMP for any of these species. Procedures for determining the initial annual amounts are found in § 655.22.

These specifications are unchanged from the proposed specifications that were published in the Federal Register on December 21, 1995 (60 FR 66249). The following table contains the final 1996 initial specifications for Atlantic mackerel, *Loligo* and *Illex* squids, and butterfish.**FINAL INITIAL SPECIFICATIONS FOR ATLANTIC MACKEREL, SQUID, AND BUTTERFISH FOR THE FISHING YEAR JANUARY 1 THROUGH DECEMBER 31, 1996 (mt)**

Specifications	Squids		Atlantic Mackerel	Butterfish
	Loligo	Illex		
Max OY <sup>1</sup> .....	44,000	30,000	<sup>2</sup> N/A	16,000
ABC <sup>3</sup> .....	30,000	30,000	1,175,500	7,200
IOY .....	25,000	21,000	105,500	5,900
DAH .....	25,000	21,000	<sup>4</sup> 105,500	5,900
DAP .....	25,000	21,000	50,000	5,900
JVP .....	0	0	35,000	0
TALFF .....	0	0	0	0

<sup>1</sup> Max optimum yield (OY) as stated in the FMP.<sup>2</sup> Not applicable, see the FMP.<sup>3</sup> IOY can increase to this amount.<sup>4</sup> Contains 20,500 mt projected recreational catch based on the formula contained in the regulations (50 CFR part 655).

This document also announces four special conditions that would affect any foreign joint venture fishery for Atlantic mackerel, should one occur in 1996: (1) Joint ventures are allowed south of 37°30' N. lat., but river herring bycatch may not exceed 0.25 percent of the over-the-side transfers of Atlantic mackerel; (2) the Regional Director, Northeast Region, NMFS, will monitor fishing operations and manage harvest to reduce impacts on marine mammals in prosecuting the Atlantic mackerel fishery; (3) the mackerel OY may be increased during the year as described under § 655.21(b)(2)(v), in consultation with the Council, but the total should not exceed 125,500 mt; and (4) applications from a particular nation for a joint venture for 1996 will not be approved until the Regional Director determines, based on an evaluation of performances, that the nation's purchase obligations for previous years have been fulfilled. There were no comments received regarding these conditions.

**Comment and Response**

One comment was received during the public comment period concerning the proposed IOY specifications for both *Illex* and *Loligo* squid.

**Comment:** The commenter urged the rejection of the proposed specifications for the squids due to the differences of 5,000 mt and 9,000 mt between the IOY and the ABC specifications for the *Loligo* and *Illex* fisheries, respectively. The commenter believed that both IOYs should be set at 30,000 mt, the ABC, because the proposed IOYs would be deleterious to New England vessels wishing to harvest squid.

**Response:** The Council provided a firm biological rationale for IOY reductions, noting that the 17th Northeast Regional Stock Assessment Workshop concluded that both squids have an annual lifespan and are susceptible to recruitment overfishing. Furthermore, the IOY is not allocated by region and New England vessels have the same harvest rights as others

participating in the fishery. Should events occur in these fisheries that would require additional IOY, the regulations at § 655.22 give the Regional Director authority to raise or lower IOY if it is beneficial to the Nation.

**Classification**

This action is authorized by 50 CFR part 655, and these final specifications are exempt from review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: February 27, 1996.

Gary Matlock,

Program Management Officer, National Marine Fisheries Service.

[FR Doc. 96-4999 Filed 3-4-96; 8:45 am]

BILLING CODE 3510-22-P

**50 CFR Part 661**

[Docket No. 950426116-5116-01; I.D. 022796C]

**Ocean Salmon Fisheries Off the Coasts of Washington, Oregon, and California; Inseason Adjustment, Point Arena, CA, to the U.S.-Mexican Border**

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Inseason adjustment; request for comments.

**SUMMARY:** NMFS announces that the retention of coho salmon will be prohibited in the recreational salmon fishery in the area from Point Arena, CA, to the U.S.-Mexican border when the season opens on March 2, 1996. This adjustment is intended to ensure conservation of coho salmon.

**DATES:** Effective 0001 hours local time, March 2, 1996, until the effective date of the 1996 management measures, as published in the *Federal Register*. Comments will be accepted through March 15, 1996.

**ADDRESSES:** Comments may be mailed to William Stelle, Jr., Director, Northwest Region, National Marine Fisheries Service, NOAA, 7600 Sand Point Way NE., BIN C15700-Bldg. 1, Seattle, WA 98115-0070; or Hilda Diaz-Soltero, Director, Southwest Region, National Marine Fisheries Service, NOAA, 501 W. Ocean Boulevard, Suite 4200, Long Beach, CA 90802-4213. Information relevant to this action has been compiled in aggregate form and is available for public review during business hours at the office of the Director, Northwest Region, NMFS (Regional Director).

**FOR FURTHER INFORMATION CONTACT:** William L. Robinson, 206-526-6140, or Rodney R. McInnis, 310-980-4030.

**SUPPLEMENTARY INFORMATION:** In the 1995 annual management measures for ocean salmon fisheries, NMFS announced 1996 recreational salmon seasons opening earlier than May 1, 1996 (60 FR 21746, May 3, 1995). The 1996 recreational fishery in the area between Point Arena, CA, and the U.S.-Mexican border is scheduled to open on March 2 (the nearest Saturday to March 1) for all salmon, unless an evaluation indicates low coho abundance in 1996, in which case inseason action may be taken to prohibit retention of coho salmon.

The best available information on February 6 indicated that the 1996 preseason index abundance estimate for Oregon Production Index (OPI) area

coho stocks is 427,300 fish, about 4 percent below the 1995 preseason estimate of 443,000 fish. In 1994 and 1995, preseason abundance estimates for Oregon coastal natural (OCN) coho salmon, an OPI area stock component, were at record low levels, resulting in no coho retention south of Cape Falcon, OR, when commercial and recreational salmon seasons opened May 1. Due to the continuing low preseason abundance estimates for OPI coho and OCN coho in 1996, it is necessary to modify the recreational fishery in the area between Point Arena, CA, and the U.S.-Mexican border such that it will open on March 2 for all salmon except coho.

Modifications in the species which may be caught and landed during specific seasons and the establishment or modification of limited retention regulations are authorized by regulations at 50 CFR 661.21(b)(1)(ii). All other restrictions that apply to this fishery remain in effect as announced in the annual management measures.

The Regional Director consulted with representatives of the Pacific Fishery Management Council and the California Department of Fish and Game regarding this adjustment. The State of California will also prohibit retention of coho salmon in the recreational fishery in State waters adjacent to this area of the exclusive economic zone. Because of the need for immediate action to conserve coho salmon, NMFS has determined that good cause exists to take this action without affording a prior opportunity for public comment. This action does not apply to other fisheries that may be operating in other areas.

**Classification**

This action is authorized by 50 CFR 661.21 and 661.23 and is exempt from review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: February 29, 1996.

Richard W. Surdi,

*Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.*

[FR Doc. 96-5100 Filed 2-29-96; 4:00 pm]

BILLING CODE 3510-22-F

**50 CFR Part 675**

[Docket No. 960129019-6019-01; I.D. 022396G]

**Groundfish of the Bering Sea and Aleutian Islands Area; Pacific Ocean Perch in the Central Aleutian District**

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

**ACTION:** Modification of a closure.

**SUMMARY:** NMFS is opening directed fishing for Pacific ocean perch in the Central Aleutian District of the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to fully utilize the total allowable catch (TAC) of Pacific ocean perch in this area.

**EFFECTIVE DATE:** 12 noon, Alaska local time (A.l.t.), February 29, 1996, until 12 midnight, A.l.t., December 31, 1996.

**FOR FURTHER INFORMATION CONTACT:** Andrew N. Smoker, 907 586-7228.

**SUPPLEMENTARY INFORMATION:** The groundfish fishery in the BSAI exclusive economic zone is managed by NMFS according to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson Fishery Conservation and Management Act. Fishing by U.S. vessels is governed by regulations implementing the FMP at 50 CFR parts 620 and 675.

In accordance with § 675.20(a)(7)(ii), the Final 1996 Harvest Specifications of Groundfish (61 FR 4311, February 5, 1996) for the BSAI established 2,571 metric tons (mt) as the initial TAC catch of Pacific ocean perch for the Central Aleutian District. At the same time, the directed fishery for Pacific ocean perch in the Central Aleutian District was closed to directed fishing under § 675.20(a)(8) in order to reserve amounts anticipated to be needed for incidental catch in other fisheries. NMFS has determined that as of February 10, 1996, 2,571 mt remain unharvested.

The Director, Alaska Region, NMFS, has determined that the 1996 TAC for Pacific ocean perch in the Central Aleutian District has not been reached. Therefore, NMFS is terminating the previous closure and is reopening directed fishing for Pacific ocean perch in the Central Aleutian District.

All other closures remain in full force and effect.

**Classification**

This action is taken under § 675.20 and is exempt from review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: February 27, 1996.  
Richard W. Surdi,  
*Acting Director, Office of Fisheries  
Conservation and Management, National  
Marine Fisheries Service.*  
[FR Doc. 96-4997 Filed 2-28-96; 3:58 pm]  
BILLING CODE 3510-22-F

## 50 CFR Part 675

[Docket No. 960129019-6019-01; I.D.  
022396F]

### Groundfish of the Bering Sea and Aleutian Islands Area; Pacific Ocean Perch in the Eastern Aleutian District

**AGENCY:** National Marine Fisheries  
Service (NMFS), National Oceanic and  
Atmospheric Administration (NOAA),  
Commerce.

**ACTION:** Modification of a closure.

**SUMMARY:** NMFS is opening directed  
fishing for Pacific ocean perch in the  
Eastern Aleutian District of the Bering  
Sea and Aleutian Islands management  
area (BSAI). This action is necessary to  
fully utilize the total allowable catch  
(TAC) of Pacific ocean perch in this  
area.

**EFFECTIVE DATE:** 12 noon, Alaska local  
time (A.l.t.), February 29, 1996, until 12  
midnight, A.l.t., December 31, 1996.

**FOR FURTHER INFORMATION CONTACT:**  
Andrew N. Smoker, 907 586-7228.

**SUPPLEMENTARY INFORMATION:** The  
groundfish fishery in the BSAI exclusive  
economic zone is managed by NMFS  
according to the Fishery Management  
Plan for the Groundfish Fishery of the  
Bering Sea and Aleutian Islands Area  
(FMP) prepared by the North Pacific  
Fishery Management Council under  
authority of the Magnuson Fishery  
Conservation and Management Act.  
Fishing by U.S. vessels is governed by  
regulations implementing the FMP at 50  
CFR parts 620 and 675.

In accordance with § 675.20(a)(7)(ii),  
the Final 1996 Harvest Specifications of  
Groundfish (61 FR 4311, February 5,  
1996) for the BSAI established 2,571  
metric tons (mt) as the initial total  
allowable catch of Pacific ocean perch  
for the Eastern Aleutian District. At the  
same time, the directed fishery for  
Pacific ocean perch in the Eastern  
Aleutian District was closed to directed  
fishing under § 675.20(a)(8) in order to  
reserve amounts anticipated to be

needed for incidental catch in other  
fisheries. NMFS has determined that as  
of February 10, 1996, 2,485 mt remain  
unharvested.

The Director, Alaska Region, NMFS,  
has determined that the 1996 TAC for  
Pacific ocean perch in the Eastern  
Aleutian District has not been reached.  
Therefore, NMFS is terminating the  
previous closure and is reopening  
directed fishing for Pacific ocean perch  
in the Eastern Aleutian District.

All other closures remain in full force  
and effect.

#### Classification

This action is taken under § 675.20  
and is exempt from review under E.O.  
12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: February 27, 1996.

Richard W. Surdi,  
*Acting Director, Office of Fisheries  
Conservation and Management, National  
Marine Fisheries Service.*  
[FR Doc. 96-4996 Filed 2-28-96; 3:58 pm]  
BILLING CODE 3510-22-F



# Proposed Rules

Federal Register

Vol. 61, No. 44

Tuesday, March 5, 1996

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## NATIONAL CREDIT UNION ADMINISTRATION

### 12 CFR Part 703

#### Investment and Deposit Activities

**AGENCY:** National Credit Union Administration (NCUA).

**ACTION:** Proposed Rule; extension of comment period.

**SUMMARY:** On November 29, 1995 (60 FR 61219) the National Credit Union Administration (NCUA) published a rule regarding natural person credit union investment and deposit activities. The comment period for this proposed rule was to have expired on March 28, 1996. To encourage additional comments, the NCUA Board has decided to extend the comment period on the proposed rule for an additional 90 days. The extended comment period now expires June 26, 1996.

**DATES:** The comment period has been extended and now expires June 26, 1996. Comments must be received on or before June 26, 1996.

**ADDRESSES:** Comments should be directed to Becky Baker, Secretary of the Board. Mail or hand-deliver comments to: National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314-3428. Fax comments to (703) 518-6319. Post comments on NCUA's electronic bulletin board by dialing (703) 518-6480. Please send comments by one method only.

**FOR FURTHER INFORMATION CONTACT:** David M. Marquis, Director, Office of Examination and Insurance, (703) 518-6360, or Daniel Gordon, Senior Investment Officer, (703) 518-6620, or at the above address.

By the National Credit Union Administration Board on February 23, 1996.  
Becky Baker,  
Secretary of the Board.

[FR Doc. 96-5110 Filed 3-4-96; 8:45 am]

BILLING CODE 7535-01-P

## FEDERAL TRADE COMMISSION

### 16 CFR Part 405

#### Trade Regulation Rule on Misbranding and Deception as to Leather Content of Waist Belts

**AGENCY:** Federal Trade Commission.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Federal Trade Commission ("Commission") announces the commencement of a rulemaking proceeding for the trade regulation rule on Misbranding and Deception as to Leather Content of Waist Belts ("Leather Belt Rule" or "Rule"). The proceeding will address whether or not the Leather Belt Rule should be repealed. The Commission invites interested parties to submit written data, views, and arguments on how the Rule has affected consumers, businesses and others, and on whether there currently is a need for the Rule. This document includes a description of the procedures to be followed, an invitation to submit written comments, a list of questions and issues upon which the Commission particularly desires comments, and instructions for prospective witnesses and other interested persons who desire to participate in the proceeding.

**DATES:** Written comments must be submitted on or before April 4, 1996.

Notifications of interest in testifying must be submitted on or before April 4, 1996. If interested parties request the opportunity to present testimony, the Commission will publish a document in the Federal Register stating the time and place at which the hearings will be held and describing the procedures that will be followed in conducting the hearings. In addition to submitting a request to testify, interested parties who wish to present testimony must submit, on or before April 4, 1996, a written comment or statement that describes the issues on which the party wishes to testify and the nature of the testimony to be given.

**ADDRESSES:** Written comments and requests to testify should be submitted to Office of the Secretary, Federal Trade Commission, Room H-159, Sixth Street and Pennsylvania Avenue, NW., Washington, DC 20580, telephone number (202) 326-2506. Comments and requests to testify should be identified at "16 CFR Part 405—Comment—

Leather Belt Rule" and "16 CFR Part 405—Request to Testify—Leather Belt Rule," respectively. If possible, submit comments both in writing and on a personal computer diskette in Word Perfect or other word processing format (to assist in processing, please identify the format and version used). Written comments should be submitted, when feasible and not burdensome, in five copies.

**FOR FURTHER INFORMATION CONTACT:** Lemuel Dowdy or Edwin Rodriguez, Attorneys, Federal Trade Commission, Division of Enforcement, Bureau of Consumer Protection, Sixth Street and Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326-2981 or (202) 326-3147.

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

Pursuant to the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. 41-58, and the Administrative Procedure Act, 5 U.S.C. 551-59, 701-06, by this Notice of Proposed Rulemaking ("NPR") the Commission initiates a proceeding to consider whether the Leather Belt Rule should be repealed or remain in effect.<sup>1</sup> The Commission is undertaking this rulemaking proceeding as part of the Commission's ongoing program of evaluating trade regulation rules and industry guides to determine their effectiveness, impact, cost and need. This proceeding also responds to President Clinton's National Regulatory Reinvention Initiative, which, among other things, urges agencies to eliminate obsolete or unnecessary regulations.

##### II. Background Information

The Leather Belt Rule was promulgated on June 27, 1964, to remedy deceptive practices involving misrepresentations about the leather content of waist belts that are not offered for sale as part of a garment. The Rule prohibits representations that belts not made from the hide or skin of an animal are made of leather or that belts are made of a specified animal hide or skin when such is not the case. In addition, the Rule requires that belts

<sup>1</sup> In accordance with section 18 of the FTC Act, 15 U.S.C. 57a, the Commission submitted this NPR to the Chairman of the Committee on Commerce, Science, and Transportation, United States Senate, and the Chairman of the Subcommittee on Commerce, Trade and Hazardous Materials, United States House of Representatives, 30 days prior to its publication in the Federal Register.

made of split leather, and ground, pulverized or shredded leather bear a label or tag disclosing the kind of leather of which the belt is composed. The Rule also requires that non-leather belts having the appearance of leather bear a tag or label disclosing their composition or disclosing that they are not leather.

As part of its continuing review of its trade regulation rules to determine their current effectiveness and impact, the Commission published a Federal Register notice<sup>2</sup> on March 27, 1995,<sup>3</sup> asking questions about the benefits and burdens of the Rule to consumers and industry. The request for comments elicited ten comments.<sup>4</sup> Six comments were from consumers<sup>5</sup> and four from leather or leather goods manufacturers.<sup>6</sup>

The consumer comments expressed continuing support for the Rule, contending that its disclosure requirements help consumers make informed purchasing decisions. One industry comment supported the Rule for the same reason.<sup>7</sup> These commenters stated that the Rule helps consumers identify belts made of different types of cowhide leather, such as top grain leather, and split leather.<sup>8</sup> In addition, the comments stated that the disclosures required by the Rule allow consumers to identify belts made of vinyl, plastic, polyurethane, paper and other synthetic materials that can be made to look like

leather.<sup>9</sup> The consumer commenters stated that, without the required disclosures, consumers cannot be certain of the quality of the leather used in belts, or that belts are made of leather at all.<sup>10</sup>

Three comments recommended that the Commission amend the Rule to allow the use of the term "bonded leather" when a leather good is made of ground, pulverized, or shredded leather that is bonded with an adhesive.<sup>11</sup> Seven comments supported the continuation of the Leather Belt Rule as it currently exists.<sup>12</sup> Two comments from industry members expressed support for consolidating the Rule and the Guides into one set of guidelines that apply to all finished leather goods.<sup>13</sup>

On September 18, 1995, the Commission announced that, to eliminate unnecessary duplication, it had rescinded the three separate guides for various leather products<sup>14</sup> and sought comment on one set of proposed, consolidated guidelines: the Guides for Select Leather and Imitation Leather Products.<sup>15</sup> Because the proposed Guides would cover belts, the Commission published, on the same day, an Advance Notice of Proposed Rulemaking ("ANPR") stating that it had tentatively determined that a separate Leather Belt Rule is no longer

necessary, and seeking comments on the proposed repeal of the Rule.<sup>16</sup> In accordance with section 18 of the FTC Act, 14 U.S.C. 57a, the ANPR was sent to the Chairman of the Committee on Commerce, Science, and Transportation, United States Senate, and the Chairman of the Subcommittee on Commerce, Trade and Hazardous Materials, United States House of Representatives.

The ANPR comment period closed on October 18, 1995. The Commission received two comments in response to the ANPR.<sup>17</sup> One of these comments supports retention of the existing Leather Belt Rule. The commenter believes that rescission of the Rule may decrease the accuracy of the labeling of waist belts, making the selection and purchase of belts more difficult for consumers.<sup>18</sup> The other comment supports consolidating the Rule into one set of guidelines governing disclosures of the leather content of leather goods, and recommends that the term "bonded leather" be allowed by those guidelines.<sup>19</sup>

After reviewing the comments submitted, the Commission has determined that the benefits of the Rule are retained through the inclusion of belts in the proposed Guides for Select Leather and Imitation Leather Products. While repealing the Rule would eliminate the Commission's ability to obtain civil penalties for any future misrepresentations of the leather content of belts, the Commission has determined that it would not seriously jeopardize the Commission's ability to act effectively. Any significant problems that might arise could be addressed on a case-by-case basis, administratively under Section 5 of the FTC Act, 15 U.S.C. 45, or through court actions under Section 13(b), 15 U.S.C. 53(b), in federal district court. Prosecuting serious or knowing misrepresentations in district court allows the Commission to seek injunctive relief as well as equitable remedies, such as redress or disgorgement.

The Commission believes that the proposed Guides serve the public

<sup>2</sup> 60 FR 15725. The Commission's Office of the Secretary has assigned document number B172445 to this notice. All comments submitted in response to this notice are sequentially numbered and filed under number B172445 in the public record, starting with number B17244500001. Any request for copies or inspection of the comments to this notice should refer to document number B172445.

<sup>3</sup> On the same date, the Commission published a Federal Register notice soliciting comment on its Industry Guides for luggage, shoes, and Ladies' handbags. 60 FR 15724. See Guides for the Luggage and Related Products Industry, 16 CFR Part 24; Guides for Shoe Content Labeling and Advertising, 16 CFR Part 231; and Guides for the Ladies' Handbag Industry, 16 CFR Part 247.

<sup>4</sup> For purposes of this NPR, we cite these ten comments using the name of the commenter and the sequential number of the comment in parentheses, without repeating the B172445 prefix.

<sup>5</sup> The following is a list of the consumer commenters: Stephen Toso (1), Ross E. Kettering (2), Matt Anderson (3), Marilyn Raeth (4), James A. McGarry (5), and Lenna Mae Gara (8).

<sup>6</sup> The following is a list of comments received from industry members: Enger Kress Company (manufactures mens and ladies wallets and occasionally leather belts) (6), Cromwell leather Company, Inc. (produces leather that is sold to producers of finished leather goods) (7), Humphreys, Inc. (manufacturer of leather belts) (9), and Leather Industries of America, Inc. (trade association representing the leather tanning industry) (10).

<sup>7</sup> Enger Kress (6).

<sup>8</sup> Toso (1), Kettering (2), Anderson (3), Raeth (4), McGarry (5), and Gara (6).

<sup>9</sup> Toso (1) states that the use in belts of synthetic materials that look like leather makes it difficult to determine the true leather content of belts. The comment gives as an example the use of "P.U. Glove Leather" where the "P.U." stands for polyurethane. Kettering (2) also opposes rescinding the Leather Belt Rule because of the difficulty consumers face in identifying belts that are made of real leather when manufacturers try to pass off vinyl or other materials as leather; the comment states that the Rule's disclosures allow consumers to make informed choices by identifying the leather contents of belts. Anderson (3), p.2.

<sup>10</sup> Toso (1) states that the discount stores are growing and that they will be tempted to deceive consumers by claiming that belts are made a higher quality leather than they actually are. Raeth (4) expresses the concern that manufacturers may pass off cheaper, inferior goods to consumers if the Rule is eliminated.

<sup>11</sup> Cromwell (7), Humphreys (9), and Leather Industries (10). These commenters recommend that the Rule include a prohibition on the use of the term "bonded leather" unless at least 75% of the fibers in the product are leather. This issue has been addressed in the proposed Guides, which allow the use of the term "bonded leather" if certain required disclosures are made.

<sup>12</sup> Toso (1), Kettering (2), Anderson (3), Raeth (4), McGarry (5), Enger Kress (6), and Gara (8).

<sup>13</sup> Cromwell (7) and Leather Industries (10).

<sup>14</sup> 60 FR 48027.

<sup>15</sup> 60 FR 48056. In particular the Commission sought comment as to whether the consolidated Guides should cover leather, or imitation leather, products in addition to shoes, luggage, handbags, and belts. The deadline for comment on the proposed Guides was October 18, 1995, but it was subsequently extended until November 15, 1995. 60 FR 54316 (Oct. 23, 1995).

<sup>16</sup> 60 FR 48070. The Commission's Office of the Secretary has assigned document number B183789 to the ANPR. All comments submitted in response to the ANPR are sequentially numbered and filed under document number B183789 in the public record, starting with number B18378900001. The comments submitted in response to the ANPR are identified in this NPR by the name of the commenter and the sequential number, without repeating the document number.

<sup>17</sup> The comments were submitted by Larry E. Gundersen (1), a consumer, and Humphreys Inc. (2), a manufacturer of leather belts.

<sup>18</sup> Gundersen (1).

<sup>19</sup> Humphreys Inc. (2). See footnote 11 above regarding the term "bonded leather."

interest better than maintaining a Rule for leather belts and separate Guides for various other leather products. Accordingly, the Commission has determined that a separate Leather Belt Rule is not necessary. The Commission therefore seeks comments on the proposed repeal of the Leather Belt Rule.

### III. Rulemaking Procedures

The Commission finds that the public interest will be served by using expedited procedures in this proceeding. First, there do not appear to be any material issues of disputed fact to resolve in determining whether to repeal the Rule. Second, the use of expedited procedures will support the Commission's goal of eliminating obsolete or unnecessary regulations without an undue expenditure of resources, while ensuring that the public has an opportunity to submit data, views and arguments on whether the Commission should repeal the Rule.

The Commission, therefore, has determined, pursuant to 16 CFR 1.20, to use the procedures set forth in this notice. These procedures include: (1) Publishing this Notice of Proposed Rulemaking; (2) soliciting written comments on the Commission's proposal to repeal the Rule; (3) holding an informal hearing, if requested by interested parties; (4) obtaining a final recommendation from staff; and (5) announcing final Commission action in a notice published in the Federal Register.

### IV. Invitation To Comment and Questions for Comment

Interested persons are requested to submit written data, views or arguments on any issue of fact, law or policy they believe may be relevant to the Commission's decision on whether to repeal the Rule. The Commission requests that commenters provide representative factual data in support of their comments. Individual firms' experiences are relevant to the extent they typify industry experience in general or the experience of similar-sized firms. Commenters opposing the proposed repeal of the Rule should explain the reasons they believe the rule is still needed and, if appropriate, suggest specific alternatives. Proposals for alternative requirements should include reasons and data that indicate why the alternatives would better protect consumers from unfair or deceptive acts or practices under section 5 of the FTC Act, 15 U.S.C. 45.

Although the Commission welcomes comments on any aspect of the proposed repeal of the Rule, the

Commission is particularly interested in comments on questions and issues raised in this Notice. All written comments should state clearly the question or issue that the commenter is addressing.

Before taking final action, the Commission will consider all written comments timely submitted to the Secretary of the Commission and testimony given on the record at any hearings scheduled in response to requests to testify. Written comments submitted will be available for public inspection in accordance with the Freedom of Information Act, 5 U.S.C. 552, and Commission regulations, on normal business days between the hours of 8:30 a.m. to 5:00 p.m. at the Federal Trade Commission, Public Reference Room, Room H-130, Federal Trade Commission, Sixth Street and Pennsylvania Avenue, N.W., Washington, DC 20580, telephone number (202) 326-2222.

### Questions

(1) Is the misrepresentation of the leather contents of belts by manufacturers and distributors of belts still a significant problem in the marketplace?

(2) What benefits do consumers derive from the Rule?

(3) Should the Rule be kept in effect or should it be repealed?

(4) How would repealing the Rule affect the benefits experienced by consumers?

(5) How would repealing the Rule affect the benefits and burdens experienced by firms subject to the Rule's requirements?

(6) Are there any other federal or state laws or regulations, or private industry standards, that eliminate the need for the Rule?

(7) Are the proposed Guides for Select Leather and Imitation Leather Products likely to provide all or most of the benefits now provided by the Rule?

(8) How, if at all, would repeal of the Rule, and the resulting elimination of civil penalty enforcement actions now available to enforce it, likely affect the accuracy of the advertising, labeling, or marketing of leather belts?

### V. Requests for Public Hearings

Because there does not appear to be any dispute as to the material facts or issues raised by this proceeding and because written comments appear adequate to present the views of all interested parties, a public hearing has not been scheduled. If any person would like to present testimony at a public hearing, he or she should follow

the procedures set forth in the **DATES** and **ADDRESSES** sections of this notice.

### VI. Preliminary Regulatory Analysis

The Regulatory Flexibility Act ("RFA"), 5 U.S.C. 601-11, requires an analysis of the anticipated impact of the proposed repeal of the Rule on small businesses.<sup>20</sup> The analysis must contain, as applicable, a description of the reasons why action is being considered, the objectives of and legal basis for the proposed action, the class and number of small entities affected, the projected reporting, recordkeeping and other compliance requirements being proposed, any existing federal rules which may duplicate, overlap or conflict with the proposed action, and any significant alternatives to the proposed action that accomplish its objectives and, at the same time, minimize its impact on small entities.

A description of the reasons why action is being considered and the objectives of the proposed repeal of the Rule have been explained elsewhere in this Notice. Repeal of the Rule would appear to have little or no effect on any small business. The Commission is not aware of any existing federal laws or regulations that would conflict with repeal of the Rule.

In light of these reasons, the Commission certifies, pursuant to section 605 of RFA, 5 U.S.C. 605, that if the Commission determines to repeal the Rule that action will not have a significant impact on a substantial number of small entities. To ensure that no substantial economic impact is being overlooked, however, the Commission requests comments on this issue. After reviewing any comments received, the Commission will determine whether it is necessary to prepare a final regulatory flexibility analysis.

### VII. Paperwork Reduction Act

The Leather Belt Rule imposes third-party disclosure requirements that constitute "information collection requirements" under the Paperwork

<sup>20</sup> Section 22 of the FTC Act, 15 U.S.C. 57b-3, also requires the Commission to issue a preliminary regulatory analysis relating to proposed rules when the Commission publishes a notice of proposed rulemaking. The Commission has determined that a preliminary regulatory analysis is not required by section 22 in this proceeding because the Commission has no reason to believe that repeal of the Rule: (1) will have an annual effect on the national economy of \$100,000,000 or more; (2) will cause a substantial change in the cost or price of goods or services that are used extensively by particular industries, that are supplied extensively in particular geographical regions, or that are acquired in significant quantities by the Federal Government, or by State or local governments; or (3) otherwise will have a significant impact upon persons subject to the Rule or upon consumers.

Reduction Act, 44 U.S.C. 3501 *et seq.* Accordingly, repeal of the Rule would eliminate any burdens on the public imposed by these disclosure requirements.

#### VIII. Additional Information for Interested Persons

##### A. Motions or Petitions

Any motions or petitions in connection with this proceeding must be filed with the Secretary of the Commission.

##### B. Communications by Outside Parties to Commissioners or Their Advisors

Pursuant to Rule 1.18(c) of the Commission's Rules of Practice, 16 CFR 1.18(c), communications with respect to the merits of this proceeding from any outside party to any Commissioner or Commissioner's advisor during the course of this rulemaking shall be subject to the following treatment. Written communications, including written communications from members of Congress, shall be forwarded promptly to the Secretary for placement on the public record. Oral communications, not including oral communications from members of Congress, are permitted only when such oral communications are transcribed verbatim or summarized at the discretion of the Commissioner or Commissioner's advisor to whom such oral communications are made, and are promptly placed on the public record, together with any written communications relating to such oral communications. Memoranda prepared by a Commissioner or Commissioner's advisor setting forth the contents of any oral communications from members of Congress shall be placed promptly on the public record. If the communication with a member of Congress is transcribed verbatim or summarized, the transcript or summary will be placed promptly on the public record.

##### List of Subjects in 16 CFR Part 405

Advertising, Clothing, Labeling, Leather and leather products industry, Trade practices.

Authority: 15 U.S.C. 41-58.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 96-5043 Filed 3-4-96; 8:45 am]

BILLING CODE 6750-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**21 CFR Parts 54, 312, 314, 320, 330, 601, 807, 812, 814, and 860**

[Docket No. 93N-0445]

#### Financial Disclosure by Clinical Investigators; Reopening of Comment Period and Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule; reopening of comment period and notice of meeting.

**SUMMARY:** The Science Board to the Food and Drug Administration (FDA), an FDA advisory committee, will hold an open committee meeting to discuss the proposed rulemaking on Financial Disclosure by Clinical Investigators, which published in the Federal Register of September 22, 1994. At the same time, FDA is reopening the comment period for the proposed rule. The proposed rule would require that the sponsor of any drug, biological product, or device submit certain information concerning the compensation to, and financial interests of, any clinical investigator conducting clinical studies to determine whether that product meets the marketing requirements specified by the agency. FDA is taking these actions in order to obtain additional comment on whether the provision on "significant payments of other sorts" should be eliminated from the proposed rule.

**DATES:** The comment period is reopened until April 29, 1996. Those desiring to make formal presentations to the Science Board must notify the contact person before March 14, 1996, and submit a brief statement of the general nature of the evidence or arguments they may wish to present, and the names and addresses of proposed participants. Each presenter will be limited in time and not all requests to speak may be able to be accommodated. All written statements submitted in a timely fashion will be provided to the board.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. The meeting will be held at the Sheraton National Hotel, North Ballroom, 900 South Orme St. (Columbia Pike and Washington Blvd.), Arlington, VA.

**FOR FURTHER INFORMATION CONTACT:** Mary Gross, Office of External Affairs

(HF-24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 20857, 301-827-3440; or the FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area) Science Board to the Food and Drug Administration, code 12603. **SUPPLEMENTARY INFORMATION:** In the Federal Register of September 22, 1994 (59 FR 48708), FDA proposed regulations to require that the sponsor of any drug, biological product, or device submit certain information concerning the compensation to, and financial interests of any clinical investigator conducting clinical studies to determine whether that product meets the marketing requirements specified by the agency. The agency is proposing to require that sponsors either certify to the absence of certain financial interests of clinical investigators or disclose those financial interests when clinical studies are submitted to FDA in support of product marketing.

FDA has asked the Science Board to discuss, at the March 29, 1996, meeting proposed § 54.4(a)(2)(ii), which would require disclosure by clinical investigators of "significant payments of other sorts" from sponsors. The proposed definition of such payments is "\* \* \* payments that exceed \$5,000 (e.g., grants to fund ongoing research, compensation in the form of equipment on retainers for ongoing consultation, or honoraria) or that exceed 5 percent of the total equity in a publicly held and widely traded company." FDA specifically seeks discussion of the following issues:

(1) In proposing to require disclosure of any significant equity interest held by a clinical investigator in the sponsor, the agency has defined a significant equity interest as "any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices, or any equity interest in a publicly traded corporation that exceeds 5 percent of total equity." Is 5 percent equity interest in a publicly traded corporation an appropriate threshold to trigger disclosure of financial information to FDA? Should a threshold dollar amount also be specified? If so, what might be a reasonable threshold amount?

(2) Are there financial arrangements that may be overlooked that could affect study outcome if FDA eliminates the provision entitled "significant payments of other sorts," from the proposed rule?

(3) Does it help to narrow the scope of the provision "significant payments of other sorts" by raising the current payment level that would trigger

disclosure of this information from \$5,000 to \$50,000 annually? Are there other options that allow retention of the provision but effectively narrow its scope?

These issues will be discussed at the March 29, 1996, advisory committee meeting. Because FDA wants to provide adequate time for the submission of all relevant information related to this important public health issue, FDA is reopening the comment period.

Interested persons may, on or before April 29, 1996, submit to Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

For further information on the administrative procedure for holding the Science Board to the Food and Drug Administration meeting and the general function of this advisory committee, see the document entitled "Advisory Committee; notice of meeting," that published in the Federal Register of February 26, 1996 (61 FR 7117).

Dated: February 27, 1996.

William K. Hubbard,

*Associate Commissioner for Policy Coordination.*

[FR Doc. 96-5116 Filed 3-4-96; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**21 CFR Parts 1300, 1301, 1302, 1303, 1304, 1305, 1306, 1307, 1308, 1309, 1310, 1311, 1312, 1313, and 1316**

[DEA Number 139P]

RIN Number 1117-AA33

### Consolidation, Elimination, and Clarification of Various Regulations

**AGENCY:** Drug Enforcement Administration (DEA), Justice.

**ACTION:** Proposed rule.

**SUMMARY:** DEA proposes to amend the language in title 21, Code of Federal Regulations, parts 1300 through 1316. In concert with the President's National Performance Review, Regulatory Reinvention Initiative (NPR), DEA proposes to consolidate, eliminate, and clarify many of its regulations to address areas of confusion frequently raised by

the pharmaceutical, chemical, and health care industries; and to correct inaccurate citations, office designations, and typographical errors.

**DATES:** Written comments or objections must be received by July 3, 1996.

**ADDRESSES:** Comments and objections should be submitted in quintuplicate to the Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/CCR.

**FOR FURTHER INFORMATION CONTACT:** G. Thomas Gitchel, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307-7297.

**SUPPLEMENTARY INFORMATION:** A comprehensive review has been conducted of title 21, Code of Federal Regulations (21 CFR), parts 1300 through 1316. Title 21 contains the rules and regulations by which DEA implements the Controlled Substances Act, the Narcotic Addict Treatment Act, the Controlled Substances Import/Export Act, the Chemical Diversion and Trafficking Act, and the Domestic Chemical Diversion Control Act. These regulations are designed to detect and deter the diversion of controlled substances and listed chemicals. DEA undertook this review to update, simplify, and consolidate its regulations in concert with the President's Regulatory Reform Initiative under the NPR; to clarify areas of confusion which have been raised by the pharmaceutical, chemical, and health care industries; and to correct inaccurate citations, office designations and typographical errors. In this effort, DEA intends to reduce some of the regulatory burden on the affected industries. The changes proposed herein build upon DEA's longstanding commitment to internal self-examination, to respond to technological advances, and to work with industry to develop the most effective and least intrusive methods of preventing and detecting the diversion of controlled substances and listed chemicals.

Among the changes being proposed, which are further described below, are the consolidation into a chart of the frequency of registration, coincident activities, and fee schedules; allowing manufacturers more latitude to set individual labeling standards; reducing the frequency of ARCOS reports from monthly to quarterly, and reducing the number of transactions to be reported by manufacturers; permitting some pharmacies to file prescriptions without marking them with a red "C", to transfer prescriptions for refill purposes more

than once, and to retain faxed prescriptions as original documents for patients in home hospice care; and combining and streamlining various reporting, recordkeeping, and inventory requirements.

The following summarizes the changes proposed to be made to each part of the regulations:

#### Part 1300

DEA is proposing to move the definitions set out in 21 CFR parts 1301 through 1313 into a new part 1300. This will provide a single source for definition of the terms used in 21 CFR parts 1301 through 1313, avoiding the need for duplicate definitions in the various parts. The definitions set out in Part 1316 will remain listed in that part due to the specificity of the definitions to the subject matter of the part.

#### Part 1301

DEA is proposing to amend 21 CFR, part 1301 to provide a simple and clear set of requirements concerning the registration of manufacturers, distributors, dispensers, importers and exporters of controlled substances. In this regard, DEA is proposing to incorporate into 21 CFR, part 1301 the requirements relating to the registration of importers and exporters which were previously set out in 21 CFR, part 1311.

In order to provide easier reference to the primary regulations regarding registration (including separate registration for independent activities, coincident activities, the application forms and fees required for registration and reregistration, and the registration period for the various activities) DEA is proposing to amend 21 CFR, part 1301 to list such requirements in table form. Use of the table form allows for "at-a-glance" reference to the fundamental regulations concerning the registration requirements, rather than requiring reference to multiple pages of text in separate sections.

In addition to revising the format of 21 CFR, part 1301, DEA is proposing to transfer the definitions previously listed in § 1301.02 to the proposed new part 1300, and to remove §§ 1301.27, 1301.29, and 1301.53, relating to civil defense authorities, provisional registration of narcotic treatment programs (NTP), and waiver and modification of rules in hearings, respectively. Sections 1301.27 and 1301.29 are obsolete and § 1301.53 is duplicated by § 1316.44. With respect to civil defense authorities, DEA will continue to work with the appropriate Federal and state agencies to insure that the proper policies and procedures are in place to deal with the availability and

security of controlled substances during emergencies. Further, the fee exemption provisions (formerly in § 1301.13 and now in § 1301.21) and the provision regarding when a registrant may apply for reregistration (formerly in § 1301.31(b) and now in § 1301.13(b)) have been amended. The fee exemption provision has been amended to provide that Federal, state or local officials who must obtain an individual practitioner registration in order to carry out their official duties are exempted from the fees for registration and reregistration. This action is being taken to insure that those individual government practitioners who are not able to practice under the registration number of a hospital or clinic are subject to the same exemption as those government physicians carrying out official duties in such facilities. The reregistration provision has been amended to allow that a person registered as either a bulk manufacturer of Schedule I or II controlled substances or an importer of Schedule I or II controlled substances may apply to be reregistered no more than 120 days prior to the expiration date of his/her registration. The current limitation of no more than 60 days prior to the expiration date does not allow sufficient time prior to the applicant's expiration date to satisfy the notice and comment and hearing procedures required under §§ 1301.33 and 1301.34 of this chapter. The additional 60 days should provide sufficient time to allow for satisfaction of those requirements for most applications prior to the expiration date. However, in no circumstances will DEA grant such an applicant reregistration more than 60 days prior to the applicant's registration expiration date.

DEA is also proposing to incorporate the language found in § 1307.12 of this chapter into the coincident activities table and the language found in § 1307.14 into § 1301.62. Additionally, DEA is proposing to combine §§ 1301.62 and 1301.63 into one section and revise the new section to allow that a registration cannot be assigned or transferred unless specific, written authority has been granted by the Administration.

The proposed changes will result in a substantial restructuring of part 1301, including the redesignation of most of the sections within the part. Only the sections relating to the Security Requirements (§ 1301.71–1301.76) and Employee Screening—Non-Practitioners (§ 1301.90–1301.93) are unchanged. For the sake of clarity, DEA is proposing in the regulatory text to remove the old §§ 1301.11 through 1301.63 and replace them with new §§ 1301.11 through

1301.52. While the appearance of the new sections is significantly changed, readers should keep in mind that there are only minor changes to the specific regulatory requirements contained in the old parts 1301 and 1311.

#### Part 1302

This part contains the requirements governing the labeling and packaging of controlled substances pursuant to sections 305 and 1008(e) of the Act (21 U.S.C. 825 and 958(e)). The proposed changes made in part 1302 would move the definitions into Part 1300 for ease of reference and, in general, allow more latitude to the registrant in the design of labels for products which contain controlled substances. While continuing to require an identifiable marking on labels of a commercial container which contains a controlled substance, the proposed changes would allow the registrant to meet the requirement by its own design of a label and placement of the required symbol. Further, language regarding labeling requirements at the inception of the Controlled Substances Act (on May 1, 1971) has been proposed to be removed as no longer necessary. The effective date for implementing the labeling requirements for substances transferred or added to a schedule is proposed to be established in the final order. Finally, the requirement for sealing of a commercial package is proposed to be amended to include all controlled substances, making it consistent with the Federal Food, Drug, and Cosmetic Act, and to allow more latitude in the design of the seal, while retaining the primary purpose of a seal which is to detect tampering of the commercial package.

#### Part 1303

This part contains the procedures governing the establishment of production and manufacturing quotas for basic classes of controlled substances listed in Schedules I and II. Changes are being proposed in this part to correct inaccurate citations and typographical errors and to move the definitions to part 1300 for ease of reference.

#### Part 1304

This part sets forth inventory and recordkeeping requirements for registrants who handle controlled substances. In accordance with 21 U.S.C. 827 and 958(e), registrants who manufacture, distribute, or dispense controlled substances must maintain complete and accurate records of such substances manufactured, received, sold, delivered or otherwise disposed of. Modifications to several sections of part

1304 are being proposed to eliminate the requirement for reports which are outdated, to remove redundancies in recordkeeping and inventory requirements, to change obsolete references, and to correct typographical errors.

Section 1304.02 is proposed to be revised to remove all definitions to Part 1300.

Section 1304.03 is proposed to be revised to combine researcher activities into one paragraph, thereby eliminating redundancies in the recordkeeping requirements.

Section 1304.04 is proposed to be revised to correct a typographical error in paragraph (a), to update language in paragraph (e), and amend paragraph (h)(2) to permit pharmacies with automatic data processing systems to file Schedule III–V prescriptions without marking them with a red “C”.

Section 1304.11 is proposed to be revised to combine all general requirements for inventories thereby eliminating redundancies. Paragraphs (b) and (c) were combined and the frequency statement was revised to permit the biennial inventory to be taken on any date as long as it is within two years of the previous biennial inventory; the requirements contained in §§ 1304.12, 1304.13, 1304.14, 1304.15, 1304.16, 1304.17, 1304.18 and 1304.19 were combined and included in 1304.11. In § 1304.12, the reference to the May 1, 1971 date is proposed to be deleted. Paragraph references are proposed to be changed to reflect revisions.

Section 1304.21 paragraph (a): The May 1, 1971 date is proposed to be deleted and paragraph references changed to reflect revisions.

Sections 1304.22, 1304.23, 1304.24, 1304.25 and 1304.26 are proposed to be combined. Paragraph references are proposed to be changed to reflect revisions.

Sections 1304.31 through 1304.38 are proposed to be revised, combined, or removed to delete obsolete forms and references, and reflect changes to manufacturer reporting from existing regulations to conform with current practice. Reporting requirements are proposed to be revised to reflect changes in frequency of reporting (from monthly to quarterly) and to reduce the number of transactions (i.e., quality control samples, manufacturing waste, etc.) required to be reported by manufacturers.

#### Part 1305

This part contains the procedures governing the issuance, use, and preservation of order forms pursuant to

section 308 of the Act (21 U.S.C. 828). The changes proposed to be made in part 1305, in general, delete redundant requirements and move the definitions into part 1300 for ease of reference. Section 1305.05, Power of Attorney, is amended only to correct certain citations; however, the existing Power of Attorney format is repeated in its entirety. Additionally, the Official Order Form for Schedule I & II Controlled Substances contains instructions that need not be repeated in the regulations. Regulations requiring reporting of lost or stolen Order Forms are modified to standardize reporting to local DEA offices of responsibility.

#### Part 1306

This part contains the specific regulatory requirements for the issuance, filling, and filing of prescriptions. Changes to this part are being proposed to reduce regulatory requirements for pharmacies. Additional changes are being made to correct typographical errors in the existing text.

Section 1306.02 contains a number of definitions which are proposed to be moved to part 1300 for ease of reference.

Section 1306.11 establishes the requirements for prescriptions for controlled substances listed in Schedule II. Under § 1306.11, the length of time a pharmacy is permitted to obtain a written prescription to cover an emergency oral prescription for a Schedule II controlled substance is 72 hours. Many pharmacists have expressed the view that there often is not enough time to meet their obligation within the time permitted. DEA is therefore proposing to extend the time allowed to obtain the written prescription from 72 hours to 7 days.

This same section permits pharmacists to dispense Schedule II narcotics to patients in Long Term Care Facilities (LTCFs) pursuant to prescriptions transmitted by facsimile. The facsimile then acts as the original written prescription for recordkeeping purposes. DEA is proposing to add a paragraph to § 1306.11 to give pharmacies the same authority to fill Schedule II narcotic prescriptions transmitted by facsimile for patients in a home hospice setting as exists for patients in LTCFs. The physician issuing the prescription will be required to note that the patient is a hospice patient on the face of the faxed prescription.

Section 1306.13 contains the rules for the partial filling of Schedule II prescriptions. A prescription for a Schedule II controlled substance written for a patient in a LTCF or for a patient

with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. Section 1306.13(b) requires that prior to any subsequent partial filling the pharmacist must determine that the additional partial fillings are necessary. DEA is proposing to remove this requirement.

The requirements for Schedule III and IV controlled substances are currently delineated separately from those in Schedule V. In order to more clearly differentiate those requirements that are identical from those that are not, where appropriate, identical rules affecting the controlled substances in Schedule V are proposed to be merged with those for Schedule III and IV. DEA is proposing to add Schedule V references to § 1306.21 and delete the corresponding § 1306.31. The language in these two sections is virtually identical and, therefore, will have no effect on the requirements currently in place.

Several typographical errors and an obsolete term are proposed to be corrected in § 1306.22.

Section 1306.23, which currently allows for the partial filling of Schedule III and IV prescriptions, is proposed to be expanded to add Schedule V controlled substances.

Section 1306.25, which refers to the rules for filing Schedule III and IV prescriptions contained in § 1304.04(h), is proposed to be removed and replaced by a new paragraph (§ 1306.24(c)).

Section 1306.26 establishes the rules for the transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes. A principal requirement for transferring prescription information is that the original prescription may be transferred on a one time basis only. This limitation was and is extremely important in preventing illegal and unauthorized refills from being dispensed. The prevention of diversion through unauthorized refills is significantly impacted by the ability of pharmacists and investigators to locate and confirm the authenticity of original prescription records. However, in situations where the prescription information, to include the entire refill history, is immediately accessible to the pharmacist, some exceptions to the one time only rule are proposed.

DEA is proposing to permit pharmacies sharing a real-time, on-line electronic database, to transfer prescription information for refill purposes for Schedule III, IV, and V controlled substances as often as refills are authorized by law and the original prescription. In addition to the requirements currently imposed on

prescription transfers, it is proposed that a pharmacy filling a transferred prescription will be required to record the dates of all previous refills.

#### Part 1307

This part is a miscellaneous part which addresses the application of state law and other Federal Law, exceptions to regulations, special exceptions for manufacture and distribution of controlled substances, disposal of controlled substances, and special exempt persons. Changes to this part are being proposed to correct citation errors and omissions and to consolidate similar requirements. Section 1307.01 contains a definition which is proposed to be moved to part 1300. DEA proposes to remove § 1307.12 and include its provisions in the chart of coincident activities contained in Part 1301. DEA proposes to incorporate § 1307.14, Distribution upon discontinuance or transfer of business, with the redesignated § 1301.52, Transfer of registration. Section 1307.21 is proposed to be amended so that the requirements for reporting controlled substances to be disposed of will be uniform for all registrants regardless of whether or not they file reports to ARCOS.

#### Part 1308

This part sets forth the schedules of controlled substances and mechanisms for scheduling, rescheduling, or decontrolling a substance. Section 1308.04 is proposed to be removed as unnecessary since it is outdated. The following tables are proposed to be removed which contain information given out routinely to the industry and is available upon request: Section 1308.24—Exempt Chemical Preparations; § 1308.26—Excluded Veterinary Anabolic Steroid Implant Products; § 1308.32—Exempted prescription products; and § 1308.34—Exempt Anabolic Steroid Products. The sections will contain a reference on the procedure to request a copy of the tables.

Sections 1308.43, 1308.46, and 1308.47 relating to hearings are proposed to be removed as their requirements are already contained in part 1316. Proposed to be added to Section 1308.42 is a sentence which provides information on where to locate additional information on hearings related to this part.

#### Part 1309

Part 1309 is proposed to be amended by moving the definitions set out in § 1309.02 into part 1300. This will



provide a centralized source for all definitions for parts 1301 through 1313.

Further, §§ 1309.53 and 1309.57 are proposed to be removed, as they duplicate § 1316.44 and 1316.67 respectively. Sections 1309.54 through 1309.56 are proposed to be redesignated as §§ 1309.53 through 1309.55. In addition, §§ 1309.21 (a) and (b), 1309.25 (a) and (b), and 1309.71(a)(2) are proposed to be amended to change the citation from § 1310.01(f)(1)(iv) to § 1300.01(c)(28)(i)(D).

#### Part 1310

Part 1310 is proposed to be amended by moving the definitions set out in § 1310.01 into part 1300. Sections 1310.05 and 1310.08 will be amended to remove references to definitions in § 1310.01. Section 1310.10(a) is proposed to be amended to change the citation from § 1310.01(f)(1)(iv) to § 1300.01(c)(28)(i)(D) and §§ 1310.14(a) and 1310.15(d) are proposed to be amended to change the citation from § 1310.01(f)(1)(iv)(A) to § 1300.01(c)(28)(i)(D)(1). Finally, § 1310.09 is proposed to be removed, as this section was applicable only during the initial chemical registration period.

#### Part 1311

This part is proposed to be removed and reserved. The requirements contained in part 1311 have been incorporated into the proposed revisions to part 1301.

#### Part 1312

This part contains the procedures governing the importation, exportation, transshipment, and intransit shipment of controlled substances. Changes are being proposed in this part to correct inaccurate citations and typographical errors, to update office designations and addresses, and to move the definitions to part 1300 for ease of reference.

#### Part 1313

Part 1313 is proposed to be amended by moving the definitions set out in § 1313.02 into part 1300. In addition, §§ 1313.15, 1313.21 and 1313.24 are proposed to be amended to remove references to the definitions in § 1313.02.

#### Part 1316

This part contains the regulatory requirements and authorities related to Administrative Inspections, Protection of Researchers and Research Subjects, Enforcement Proceedings, Administrative Hearings, Seizure, Forfeiture, and Disposition of Property and Expedited Forfeiture Proceedings for Certain Property. Changes to this

part are being proposed to correct citation errors and omissions and to consolidate similar requirements. DEA proposes to revise § 1316.13 to replace the present schedule of inspections with a system where the frequency of inspections will be determined by the history of the registrant, potential for diversion, or the amount of controlled substances found in the illicit market. DEA will focus inspection resources on diversion prevention and problem areas, reducing the intended frequency of inspections of registrants with a demonstrated record of compliance. This revision only applies to distributors of controlled substances listed in Schedules II through V and manufacturers of controlled substances listed in Schedules III through V. The yearly inspection for manufacturers of controlled substances listed in Schedules I and II and distributors of controlled substances listed in Schedule I remains unchanged. This proposal is intended to reduce the expenditure of time and effort, both on the part of DEA and the registrants who have shown a history of compliance in the past and continue to comply with the requirements of the CSA.

The Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this proposed regulation and by approving it certifies that this proposed regulation will not have a significant economic impact on a substantial number of small entities. This proposed regulation will streamline the current regulations set out in title 21, Code of Federal Regulations, parts 1300 to end and to provide regulatory relief to registrants.

This proposed regulation has been drafted in accordance with Executive Order 12866, section 1(b), Principles of Regulation. The Office of Management and Budget has reviewed this proposed rule and determined that it is not a "significant regulatory action" under Executive Order 12866, section 3(f), Regulatory Planning and Review.

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

#### List of Subjects in 21 CFR Parts 1300–1316

Administrative practice and procedure, Drug traffic control, Security measures, Exports, Imports, Labeling, Packaging and containers, Reporting requirements, Prescription drugs, Narcotics, List I and List II chemicals, Research, Seizures and forfeitures.

21 CFR Part 1300 is proposed to be added to read as follows:

#### PART 1300—DEFINITIONS

##### Sec.

1300.01 Definitions relating to controlled substances.

1300.02 Definitions relating to listed chemicals.

Authority: 21 U.S.C. 802, 871(b), 951, 958(f).

#### § 1300.01 Definitions relating to controlled substances.

(a) Any term not defined in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802), except that certain terms used in part 1316 of this chapter are defined at the beginning of each subpart of that part.

(b) As used in parts 1301 through 1308 and part 1312 of this chapter, the following terms shall have the meanings specified:

(1) The term *Act* means the Controlled Substances Act, as amended (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act, as amended (84 Stat. 1285; 21 U.S.C. 951).

(2) The term *Administration* means the Drug Enforcement Administration.

(3) The term *Administrator* means the Administrator of the Drug Enforcement Administration. The Administrator has been delegated authority under the Act by the Attorney General (28 CFR 0.100).

(4) The term *anabolic steroid* means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, and corticosteroids) that promotes muscle growth, and includes:

- (i) Boldenone;
- (ii) Chlorotestosterone (4-chlorotestosterone);
- (iii) Clostebol;
- (iv) Dehydrochloromethyltestosterone;
- (v) Dihydrotestosterone (4-dihydrotestosterone);
- (vi) Drostanolone;
- (vii) Ethylestrenol;
- (viii) Fluoxymesterone;
- (ix) Formebolone (formebolone);
- (x) Mesterolone;
- (xi) Methandienone;
- (xii) Methandranol;
- (xiii) Methandriol;
- (xiv) Methandrostenolone;



(xv) Methenolone;  
 (xvi) Methyltestosterone;  
 (xvii) Mibolerone;  
 (xviii) Nandrolone;  
 (xix) Norethandrolone;  
 (xx) Oxandrolone;  
 (xxi) Oxymesterone;  
 (xxii) Oxymetholone;  
 (xxiii) Stanolone;  
 (xxiv) Stanozolol;  
 (xxv) Testolactone;  
 (xxvi) Testosterone;  
 (xxvii) Trenbolone; and  
 (xxviii) Any salt, ester, or isomer of a drug or substance described or listed in this paragraph, if that salt, ester, or isomer promotes muscle growth. Except such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for such administration. If any person prescribes, dispenses, or distributes such steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this paragraph.

(5) The term *basic class* means, as to controlled substances listed in Schedules I and II:

(i) Each of the opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, listed in § 1308.11(b) of this chapter;

(ii) Each of the opium derivatives, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in § 1308.11(c) of this chapter;

(iii) Each of the hallucinogenic substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in § 1308.11(d) of this chapter;

(iv) Each of the following substances, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(A) Opium, including raw opium, opium extracts, opium fluid extracts, powdered opium, granulated opium, deodorized opium and tincture of opium;

(B) Apomorphine;

(C) Codeine;

(D) Etorphine hydrochloride;

(E) Ethylmorphine;  
 (F) Hydrocodone;  
 (G) Hydromorphone;  
 (H) Metopon;  
 (I) Morphine;  
 (J) Oxycodone;  
 (K) Oxymorphone;  
 (L) Thebaine;  
 (M) Mixed alkaloids of opium listed in Section 1308.12(b)(2) of this chapter;  
 (N) Cocaine; and  
 (O) Ecgonine;

(v) Each of the opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, listed in § 1308.12(c) of this chapter; and

(vi) Methamphetamine, its salts, isomers, and salts of its isomers;

(vii) Amphetamine, its salts, optical isomers, and salts of its optical isomers;

(viii) Phenmetrazine and its salts;

(ix) Methylphenidate;

(x) Each of the substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in § 1308.12(e) of this chapter.

(6) The term *commercial container* means any bottle, jar, tube, ampule, or other receptacle in which a substance is held for distribution or dispensing to an ultimate user, and in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term commercial container does not include any package liner, package insert or other material kept with or within a commercial container, nor any carton, crate, drum, or other package in which commercial containers are stored or are used for shipment of controlled substances.

(7) The term *compounder* means any person engaging in maintenance or detoxification treatment who also mixes, prepares, packages or changes the dosage form of a narcotic drug listed in Schedules II, III, IV or V for use in maintenance or detoxification treatment by another narcotic treatment program.

(8) The term *Controlled Substance* has the meaning given in section 802(6) of Title 21, United States Code (U.S.C.).

(9) The term *customs territory* of the United States means the several States, the District of Columbia, and Puerto Rico.

(10) The term *detoxification* treatment means the dispensing, for a period of time as specified below, of a narcotic drug or narcotic drugs in decreasing doses to an individual to alleviate adverse physiological or psychological

effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period of time. There are two types of detoxification treatment: Short-term detoxification treatment and long-term detoxification treatment.

(i) Short-term detoxification treatment is for a period not in excess of 30 days.

(ii) Long-term detoxification treatment is for a period more than 30 days but not in excess of 180 days.

(11) The term *dispenser* means an individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance.

(12) The term *export* means, with respect to any article, any taking out or removal of such article from the jurisdiction of the United States (whether or not such taking out or removal constitutes an exportation within the meaning of the customs and related laws of the United States).

(13) The term *exporter* includes every person who exports, or who acts as an export broker for exportation of, controlled substances listed in any schedule.

(14) The term *hearing* means:

(i) In part 1301 of this chapter, any hearing held for the granting, denial, revocation, or suspension of a registration pursuant to sections 303, 304, and 1008 of the Act (21 U.S.C. 823, 824 and 958).

(ii) In part 1303 of this chapter, any hearing held regarding the determination of aggregate production quota or the issuance, adjustment, suspension, or denial of a procurement quota or an individual manufacturing quota.

(iii) In part 1308 of this chapter, any hearing held for the issuance, amendment, or repeal of any rule issuable pursuant to section 201 of the Act (21 U.S.C. 811).

(15) The term *home infusion pharmacy* means a pharmacy which compounds solutions for direct administration to a patient in a private residence, Long Term Care Facility or hospice setting by means of parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion.

(16) The term *import* means, with respect to any article, any bringing in or introduction of such article into either the jurisdiction of the United States or the customs territory of the United States, and from the jurisdiction of the United States into the customs territory of the United States (whether or not such bringing in or introduction constitutes an importation within the

meaning of the tariff laws of the United States).

(17) The term *importer* includes every person who imports, or who acts as an import broker for importation of, controlled substances listed in any schedule.

(18) The term *individual practitioner* means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

(19) The term *institutional practitioner* means a hospital or other person (other than an individual) licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

(20) The term *interested person* means any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811).

(21) The term *inventory* means all factory and branch stocks in finished form of a basic class of controlled substance manufactured or otherwise acquired by a registrant, whether in bulk, commercial containers, or contained in pharmaceutical preparations in the possession of the registrant (including stocks held by the registrant under separate registration as a manufacturer, importer, exporter, or distributor).

(22) The term *isomer* means the optical isomer, except as used in § 1308.11(d) and § 1308.12(b)(4). As used in § 1308.11(d), the term isomer means the optical, positional, or geometric isomer. As used in § 1308.12(b)(4), the term isomer means the optical or geometric isomer.

(23) The term *jurisdiction of the United States* means the customs territory of the United States, the Virgin Islands, the Canal Zone, Guam, American Samoa, and the Trust Territories of the Pacific Islands.

(24) The term *label* means any display of written, printed, or graphic matter placed upon the commercial container of any controlled substance by any manufacturer of such substance.

(25) The term *labeling* means all labels and other written, printed, or graphic matter:

(i) Upon any controlled substance or any of its commercial containers or wrappers, or

(ii) accompanying such controlled substance.

(26) The term *Long Term Care Facility (LTCF)* means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

(27) The term *maintenance treatment* means the dispensing for a period in excess of twenty-one days, of a narcotic drug or narcotic drugs in the treatment of an individual for dependence upon heroin or other morphine-like drug.

(28) The term *manufacture* means the producing, preparation, propagation, compounding, or processing of a drug or other substance or the packaging or repackaging of such substance, or the labeling or relabeling of the commercial container of such substance, but does not include the activities of a practitioner who, as an incident to his/her administration or dispensing such substance in the course of his/her professional practice, prepares, compounds, packages or labels such substance. The term *manufacturer* means a person who manufactures a drug or other substance, whether under a registration as a manufacturer or under authority of registration as a researcher or chemical analyst.

(29) The term *mid-level practitioner* means an individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. Examples of mid-level practitioners include, but are not limited to, health care providers such as nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists and physician assistants who are authorized to dispense controlled substances by the state in which they practice.

(30) The term *name* means the official name, common or usual name, chemical name, or brand name of a substance.

(31) The term *narcotic drug* means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

(i) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium.

(ii) Poppy straw and concentrate of poppy straw.

(iii) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine and derivatives of ecgonine or their salts have been removed.

(iv) Cocaine, its salts, optical and geometric isomers, and salts of isomers.

(v) Ecgonine, its derivatives, their salts, isomers and salts of isomers.

(vi) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in paragraphs (b)(31) (i) through (v) of this section.

(32) The term *narcotic treatment program* means a program engaged in maintenance and/or detoxification treatment with narcotic drugs.

(33) The term *net disposal* means, for a stated period, the quantity of a basic class of controlled substance distributed by the registrant to another person, plus the quantity of that basic class used by the registrant in the production of (or converted by the registrant into) another basic class of controlled substance or a noncontrolled substance, plus the quantity of that basic class otherwise disposed of by the registrant, less the quantity of that basic class returned to the registrant by any purchaser, and less the quantity of that basic class distributed by the registrant to another registered manufacturer of that basic class for purposes other than use in the production of, or conversion into, another basic class of controlled substance or a noncontrolled substance or in the manufacture of dosage forms of that basic class.

(34) The term *pharmacist* means any pharmacist licensed by a State to dispense controlled substances, and shall include any other person (e.g., pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State.

(35) The term *person* includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

(36) The term *prescription* means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user. (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription.)

(37) The term *proceeding* means all actions taken for the issuance, amendment, or repeal of any rule issued pursuant to section 201 of the Act (21

U.S.C. 811), commencing with the publication by the Administrator of the proposed rule, amended rule, or repeal in the Federal Register.

(38) The term *purchaser* means any registered person entitled to obtain and execute order forms pursuant to § 1305.04 and 1305.06.

(39) The term *readily retrievable* means that certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

(40) The terms *register* and *registration* refer only to registration required and permitted by sections 303 or 1007 of the Act (21 U.S.C. 823 or 957).

(41) The term *registrant* means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).

(42) The term *supplier* means any registered person entitled to fill order forms pursuant to § 1305.08.

#### **§ 1300.02 Definitions relating to listed chemicals.**

(a) Any term not defined in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802), except that certain terms used in part 1316 of this chapter are defined at the beginning of each subpart of that part.

(b) As used in parts 1309, 1310 and 1313 of this chapter, the following terms shall have the meaning specified:

(1) The term *Act* means the Controlled Substances Act, as amended (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act, as amended (84 Stat. 1285; 21 U.S.C. 951) as amended.

(2) The term *Administration* means the Drug Enforcement Administration.

(3) The term *Administrator* means the Administrator of the Drug Enforcement Administration. The Administrator has been delegated authority under the Act by the Attorney General (28 CFR 0.100).

(4) The terms *broker* and *trader* mean any individual, corporation, corporate division, partnership, association, or other legal entity which assists in arranging an international transaction in a listed chemical by—

(i) Negotiating contracts;

(ii) Serving as an agent or intermediary; or

(iii) Fulfilling a formal obligation to complete the transaction by bringing together a buyer and seller, a buyer and

transporter, or a seller and transporter, or by receiving any form of compensation for so doing.

(5) The term *chemical export* means transferring ownership or control, or the sending or taking of threshold quantities of listed chemicals out of the United States (whether or not such sending or taking out constitutes an exportation within the meaning of the Customs and related laws of the United States).

(6) The term *chemical exporter* is a regulated person who, as the principal party in interest in the export transaction, has the power and responsibility for determining and controlling the sending of the listed chemical out of the United States.

(7) The term *chemical import* means with respect to a listed chemical, any bringing in or introduction of such listed chemical into either the jurisdiction of the United States or into the Customs territory of the United States (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

(8) The term *chemical importer* is a regulated person who, as the principal party in interest in the import transaction, has the power and responsibility for determining and controlling the bringing in or introduction of the listed chemical into the United States.

(9) The term *chemical mixture* means a combination of two or more chemical substances, at least one of which is not a listed chemical, except that such term does not include any combination of a listed chemical with another chemical that is present solely as an impurity or which has been created to evade the requirements of the Act.

(10) The term *customs territory of the United States* means the several States, the District of Columbia, and Puerto Rico.

(11) The term *encapsulating machine* means any manual, semi-automatic, or fully automatic equipment which may be used to fill shells or capsules with any powdered, granular, semi-solid, or liquid material.

(12) The term *established business relationship with a foreign customer* means the regulated person has exported a listed chemical at least once within the past six months, or twice within the past twelve months to a foreign manufacturer, distributor, or end user of the chemical that has an established business in the foreign country with a fixed street address. A person or business which functions as a broker or intermediary is not a customer within the meaning of this section. The term also means that the regulated

person has provided the Administration with the following information in accordance with the Waiver of 15-day advance notice requirements of § 1313.24 of this chapter:

(i) The name and street address of the chemical exporter and of each regular customer;

(ii) The telephone number, telex number, contact person, and where available, the facsimile number for the chemical exporter and for each regular customer;

(iii) The nature of the regular customer's business (i.e., importer, exporter, distributor, manufacturer, etc.), and if known, the use to which the listed chemical or chemicals will be applied;

(iv) The duration of the business relationship;

(v) The frequency and number of transactions occurring during the preceding 12-month period;

(vi) the amounts and the listed chemical or chemicals involved in regulated transactions between the chemical exporter and regular customer;

(vii) The method of delivery (direct shipment or through a broker or forwarding agent); and

(viii) Other information that the chemical exporter considers relevant for determining whether a customer is a regular customer.

(13) The term *established record as an importer* means that the regulated person has imported a listed chemical at least once within the past six months, or twice within the past twelve months from a foreign supplier. The term also means that the regulated person has provided the Administration with the following information in accordance with the waiver of the 15-day advance notice requirements of § 1313.15 of this chapter:

(i) The name, DEA registration number (where applicable), street address, telephone number, telex number, and, where available, the facsimile number of the regulated person and of each foreign supplier; and

(ii) The frequency and number of transactions occurring during the preceding 12 month period.

(14) The term *hearing* means any hearing held for the granting, denial, revocation, or suspension of a registration pursuant to sections 303, 304, and 1008 of the Act (21 U.S.C. 823, 824 and 958).

(15) The term *international transaction* means a transaction involving the shipment of a listed chemical across an international border (other than a United States border) in which a broker or trader located in the United States participates.

(16) The term *jurisdiction of the United States* means the customs territory of the United States, the Virgin Islands, the Canal Zone, Guam, American Samoa, and the Trust Territories of the Pacific Islands.

(17) The term *listed chemical* means any List I chemical or List II chemical.

(18) The term *List I chemical* means a chemical specifically designated by the Administrator in § 1310.02(a) of this chapter that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the Act and is important to the manufacture of a controlled substance.

(19) The term *List II chemical* means a chemical, other than a List I chemical, specifically designated by the Administrator in § 1310.02(b) of this chapter that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the Act.

(20) The term *name* means the official name, common or usual name, chemical name, or brand name of a substance.

(21) The term *person* includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

(22) The term *readily retrievable* means that certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

(23) The terms *register* and *registration* refer only to registration required and permitted by sections 303 or 1007 of the Act (21 U.S.C. 823 or 957).

(24) The term *registrant* means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).

(25) The term *regular customer* means a person with whom the regulated person has an established business relationship for a specified listed chemical or chemicals that has been reported to the Administration subject to the criteria established in § 1300.01(b)(12).

(26) The term *regular importer* means, with respect to a listed chemical, a person that has an established record as an importer of that listed chemical that is reported to the Administrator.

(27) The term *regulated person* means any individual, corporation, partnership, association, or other legal

entity who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine, or who acts as a broker or trader for an international transaction involving a listed chemical, tableting machine, or encapsulating machine.

(28) The term *regulated transaction* means:

(i) A distribution, receipt, sale, importation, or exportation of a listed chemical, or an international transaction involving shipment of a listed chemical, or if the Administrator establishes a threshold amount for a specific listed chemical, a threshold amount as determined by the Administrator, which includes a cumulative threshold amount for multiple transactions, of a listed chemical, except that such term does not include:

(A) A domestic lawful distribution in the usual course of business between agents or employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person;

(B) A delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this paragraph does not relieve a distributor, importer, or exporter from compliance with this part or parts 1309 and 1313 of this chapter;

(C) Any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Administrator as excluded from this definition as unnecessary for enforcement of the Act;

(D) Any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act unless—

(i) The drug contains ephedrine or its salts, optical isomers, or salts of optical isomers as the only active medicinal ingredient or contains ephedrine or its salts, optical isomers or salts of optical isomers and therapeutically insignificant quantities of another active medicinal ingredient. For purposes of this paragraph, the term

“therapeutically insignificant quantities” shall apply if the product formulation (i.e., the qualitative and quantitative composition of active ingredients within the product) is not listed in any of the following

compendiums: *American Pharmaceutical Association (Apha) Handbook of Nonprescription Drugs; Drug Facts and Comparisons* (published by Wolters Kluwer Company); or *USP DI* (published by authority of the United States Pharmacopeial Convention, Inc.); or the product is not listed in § 1310.15 of this chapter as an exempt drug product. For drug products having formulations not found in the above compendiums, the Administrator shall determine, pursuant to a written request as specified in § 1310.14 of this chapter, whether the active medicinal ingredients are present in quantities considered therapeutically significant for purposes of this paragraph; or

(2) The Administrator has determined pursuant to the criteria in § 1310.10 of this chapter that:

(i) The drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

(ii) The quantity of ephedrine or other listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical by the Administrator;

(E) Any transaction in a chemical mixture listed in § 1310.13 of this chapter.

(ii) A distribution, importation, or exportation of a tableting machine or encapsulating machine except that such term does not include a domestic lawful distribution in the usual course of business between agents and employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person.

(29) The term *retail distributor* means a distributor whose List I chemical activities are restricted to the sale of drug products that are regulated as List I chemicals pursuant to § 1300.01(b)(28)(i)(D), directly to walk-in customers for personal use.

(30) The term *tableting machine* means any manual, semi-automatic, or fully automatic equipment which may be used for the compaction or molding of powdered or granular solids, or semi-solid material, to produce coherent solid tablets.

## PART 1301—[AMENDED]

1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877, 952, 956, 957, 958, unless otherwise noted.

2. Section 1301.01 is proposed to be revised to read as follows:

**§ 1301.01 Scope of part 1301.**

Procedures governing the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances pursuant to sections 301–304 and 1007–1008 of the Act (21 U.S.C. 821–824 and 957–958) are set forth generally by those sections and specifically by the sections of this part.

3. Section 1301.02 is proposed to be revised to read as follows:

**§ 1301.02 Definitions.**

Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or Part 1300 of this chapter.

4. As set forth in the Preamble, part 1301 is also proposed to be amended by revising §§ 1301.11 through 1301.52 and the undesignated center headings and by removing §§ 1301.53 through 1301.63 and the undesignated center headings:

**Registration****§ 1301.11 Persons required to register.**

(a) Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to §§ 1301.22–1301.26. Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.)

**§ 1301.12 Separate registrations for separate locations.**

(a) A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person.

(b) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed:

(1) A warehouse where controlled substances are stored by or on behalf of a registered person, unless such substances are distributed directly from such warehouse to registered locations other than the registered location from which the substances were delivered or to persons not required to register by virtue of subsection 302(c)(2) or

subsection 1007(b)(1)(B) of the Act (21 U.S.C. 822(c)(2) or 957(b)(1)(B));

(2) An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised but which neither contains such substances (other than substances for display purposes or lawful distribution as samples only) nor serves as a distribution point for filling sales orders; and

(3) An office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.

**§ 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.**

(a) Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Administrator to such person.

(b) Any person who is registered may apply to be reregistered not more than 60 days before the expiration date of his/her registration, except that a bulk manufacturer of Schedule I or II controlled substances or an importer of Schedule I or II controlled substances may apply to be reregistered no more than 120 days before the expiration date of their registration.

(c) At the time a manufacturer, distributor, researcher, analytical lab, importer, exporter or narcotic treatment program is first registered, that business activity shall be assigned to one of twelve groups, which shall correspond to the months of the year. The expiration date of the registrations of all registrants within any group will be the last date of the month designated for that group. In assigning any of the above business activities to a group, the Administration may select a group the expiration date of which is less than one year from the date such business activity was registered. If the business activity is assigned to a group which has an expiration date less than three months from the date of which the business activity is registered, the registration shall not expire until one year from that expiration date; in all other cases, the registration shall expire

on the expiration date following the date on which the business activity is registered.

(d) At the time a retail pharmacy, hospital/clinic, practitioner or teaching institution is first registered, that business activity shall be assigned to one of twelve groups, which shall correspond to the months of the year. The expiration date of the registrations of all registrants within any group will be the last day of the month designated for that group. In assigning any of the above business activities to a group, the Administration may select a group the expiration date of which is not less than 28 months nor more than 39 months from the date such business activity was registered. After the initial registration period, the registration shall expire 36 months from the initial expiration date.

(e) Any person who is required to be registered and who is not so registered, shall make application for registration for one of the following groups of controlled substances activities, which are deemed to be independent of each other. Application for each registration shall be made on the indicated form, and shall be accompanied by the indicated fee. Fee payments shall be made in the form of a personal, certified, or cashier's check or money order made payable to the "Drug Enforcement Administration". The application fees are not refundable. Any person, when registered to engage in the activities described in each subparagraph in this paragraph, shall be authorized to engage in the coincident activities described without obtaining a registration to engage in such coincident activities, provided that, unless specifically exempted, he/she complies with all requirements and duties prescribed by law for persons registered to engage in such coincident activities. Any person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities, except as provided in this paragraph under coincident activities. A single registration to engage in any group of independent activities listed below may include one or more controlled substances listed in the schedules authorized in that group of independent activities. A person registered to conduct research with controlled substances listed in Schedule I may conduct research with any substances listed in Schedule I for which he/she has filed and had approved a research protocol.

(1)

Business activity	Controlled substances	DEA application forms	Application fee	Registration period	Coincident activities allowed
(i) Manufacturing .....	Schedules I through V.	New—225 ... Renewal—225a.	\$875 875	1 year .....	Schedules I through V: May distribute that substance or class for which registration was issued; may not distribute any substance or class for which not registered. Schedules II through V: May conduct chemical analysis and preclinical research (including quality control analysis) with substances listed in those schedules for which authorization as a manufacturer was issued.
(ii) Distributing .....	Schedules I through V.	New—225 ... Renewal—225a.	438 438	1 year.	
(iii) Dispensing or Instructing (Includes Practitioner Hospital/Clinic, Retail Pharmacy, Teaching Institution).	Schedules II through V.	New—224 ... Renewal—224a.	210 210	3 years .....	May conduct research and instructional activities with those substances for which registration was granted, except that a mid-level practitioner may conduct such research only to the extent expressly authorized under state statute. A pharmacist may manufacture an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in Schedule II through V in a proportion not exceeding 20 percent of the complete solution, compound, or mixture.
(iv) Research or Instructing	Schedule I ....	New—225 ... Renewal—225a.	70 70	1 year .....	A researcher may manufacture or import the basic class of substance or substances for which registration was issued, provided that such manufacture or import is set forth in the protocol required in Section 1301.18 and to distribute such class to persons registered or authorized to conduct research with such class of substance or registered or authorized to conduct chemical analysis with controlled substances.
(v) Research .....	Schedules II through V.	New—225 ... Renewal—225a.	70 70	1 year .....	May conduct chemical analysis with controlled substances in those schedules for which registration was issued; manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration or reregistration; import such substances for research purposes; distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances, and to persons exempted from registration pursuant to Section 1301.24, and to conduct instructional activities with controlled substances.
(vi) Narcotic Treatment Program (including compounder).	Narcotic Drugs in Schedules II through V.	New—363 ... Renewal—363a.	70 70	1 year.	
(vii) Importing .....	Schedules I through V.	New—225 ... Renewal—225a.	438 438	1 year .....	May distribute that substance or class for which registration was issued; may not distribute any substance or class for which not registered.
(viii) Exporting .....	Schedules I through V.	New—225 ... Renewal—225a.	438 438	1 year.	
(ix) Chemical Analysis .....	Schedules I through V.	New—225 ... Renewal—225a.	70 70	1 year .....	May manufacture and import controlled substances for analytical or instructional activities; may distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances and to persons exempted from registration pursuant to Section 1301.24; may export such substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries, and to conduct instructional activities with controlled substances.

(2) DEA Forms 224, 225, and 363 may be obtained at any area office of the Administration or by writing to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005.

(3) DEA Forms 224a, 225a, and 363a will be mailed, as applicable, to each registered person approximately 60 days before the expiration date of his/her registration; if any registered person does not receive such forms within 45 days before the expiration date of his/her registration, he/she must promptly give notice of such fact and request such forms by writing to the Registration Unit of the Administration at the foregoing address.

(f) Each application for registration to handle any basic class of controlled substance listed in Schedule I (except to conduct chemical analysis with such classes), and each application for registration to manufacture a basic class of controlled substance listed in Schedule II shall include the Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, for each basic class to be covered by such registration.

(g) Each application for registration to import or export controlled substances shall include the Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, for each controlled substance whose importation or exportation is to be authorized by such registration. Registration as an importer or exporter shall not entitle a registrant to import or export any controlled substance not specified in such registration.

(h) Each application for registration to conduct research with any basic class of controlled substance listed in Schedule II shall include the Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, for each such basic class to be manufactured or imported as a coincident activity of that registration. A statement listing the quantity of each such basic class or controlled substance to be imported or manufactured during the registration period for which application is being made shall be included with each such application. For purposes of this paragraph only, manufacturing is defined as the production of a controlled substance by synthesis, extraction or by agricultural/horticultural means.

(i) Each application shall include all information called for in the form, unless the item is not applicable, in which case this fact shall be indicated.

(j) Each application, attachment, or other document filed as part of an

application, shall be signed by the applicant, if an individual; by a partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation, corporate division, association, trust or other entity. An applicant may authorize one or more individuals, who would not otherwise be authorized to do so, to sign applications for the applicant by filing with the Registration Unit of the Administration a power of attorney for each such individual. The power of attorney shall be signed by a person who is authorized to sign applications under this paragraph and shall contain the signature of the individual being authorized to sign applications. The power of attorney shall be valid until revoked by the applicant.

#### **§ 1301.14 Filing of application; acceptance for filing; defective applications.**

(a) All applications for registration shall be submitted for filing to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005. The appropriate registration fee and any required attachments must accompany the application.

(b) Any person required to obtain more than one registration may submit all applications in one package. Each application must be complete and should not refer to any accompanying application for required information.

(c) Applications submitted for filing are dated upon receipt. If found to be complete, the application will be accepted for filing. Applications failing to comply with the requirements of this part will not generally be accepted for filing. In the case of minor defects as to completeness, the Administrator may accept the application for filing with a request to the applicant for additional information. A defective application will be returned to the applicant within 10 days following its receipt with a statement of the reason for not accepting the application for filing. A defective application may be corrected and resubmitted for filing at any time; the Administrator shall accept for filing any application upon resubmission by the applicant, whether complete or not.

(d) Accepting an application for filing does not preclude any subsequent request for additional information pursuant to § 1301.15 and has no bearing on whether the application will be granted.

#### **§ 1301.15 Additional Information.**

The Administrator may require an applicant to submit such documents or written statements of fact relevant to the

application as he/she deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.

#### **§ 1301.16 Amendments to and withdrawal of applications.**

(a) An application may be amended or withdrawn without permission of the Administrator at any time before the date on which the applicant receives an order to show cause pursuant to § 1301.37. An application may be amended or withdrawn with permission of the Administrator at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest.

(b) After an application has been accepted for filing, the request by the applicant that it be returned or the failure of the applicant to respond to official correspondence regarding the application, when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application.

#### **§ 1301.17 Special procedures for certain applications.**

(a) If, at the time of application for registration of a new pharmacy, the pharmacy has been issued a license from the appropriate State licensing agency, the applicant may include with his/her application an affidavit as to the existence of the State license in the following form:

##### **Affidavit for New Pharmacy**

I, \_\_\_\_\_, the \_\_\_\_\_ (Title of officer, official, partner, or other position) of \_\_\_\_\_ (Corporation, partnership, or sole proprietor), doing business as \_\_\_\_\_ (Store name) at \_\_\_\_\_ (Number and Street), \_\_\_\_\_ (City) \_\_\_\_\_ (State) \_\_\_\_\_ (Zip code), hereby certify that said store was issued a pharmacy permit No. \_\_\_\_\_ by the \_\_\_\_\_ (Board of Pharmacy or Licensing Agency) of the State of \_\_\_\_\_ on \_\_\_\_\_ (Date).

This statement is submitted in order to obtain a Drug Enforcement Administration registration number. I understand that if any information is false, the Administration may immediately suspend the registration for this store and commence proceedings to revoke under 21 U.S.C. 824(a) because of the danger to public health and safety. I further understand that any false information

contained in this affidavit may subject me personally and the above-named corporation/partnership/business to prosecution under 21 U.S.C. 843, the penalties for conviction of which include imprisonment for up to 4 years, a fine of not more than \$30,000 or both.

Signature (Person who signs Application for Registration) State of \_\_\_\_\_

County of \_\_\_\_\_

Subscribed to and sworn before me this \_\_\_\_\_ day of \_\_\_\_\_, 19\_\_\_\_.

#### Notary Public

(b) Whenever the ownership of a pharmacy is being transferred from one person to another, if the transferee owns at least one other pharmacy licensed in the same State as the one the ownership of which is being transferred, the transferee may apply for registration prior to the date of transfer. The Administrator may register the applicant and authorize him to obtain controlled substances at the time of transfer. Such registration shall not authorize the transferee to dispense controlled substances until the pharmacy has been issued a valid State license. The transferee shall include with his/her application the following affidavit:

#### Affidavit for Transfer of Pharmacy

I, \_\_\_\_\_, the \_\_\_\_\_ (Title of officer, official, partner or other position) of \_\_\_\_\_ (Corporation, partnership, or sole proprietor), doing business as \_\_\_\_\_ (Store name) hereby certify:

(1) That said company was issued a pharmacy permit No. \_\_\_\_\_ by the \_\_\_\_\_ (Board of Pharmacy of Licensing Agency) of the State of \_\_\_\_\_ and a DEA Registration Number \_\_\_\_\_ for a pharmacy located at \_\_\_\_\_ (Number and Street) \_\_\_\_\_ (City) \_\_\_\_\_ (State) \_\_\_\_\_ (Zip Code); and

(2) That said company is acquiring the pharmacy business of \_\_\_\_\_ (Name of Seller) doing business as \_\_\_\_\_ with DEA Registration Number \_\_\_\_\_ on or about \_\_\_\_\_ (Date of Transfer) and that said company has applied (or will apply on \_\_\_\_\_ (Date) for a pharmacy permit from the board of pharmacy (or licensing agency) of the State of \_\_\_\_\_ to do business as \_\_\_\_\_ (Store name) at \_\_\_\_\_ (Number and Street) \_\_\_\_\_ (City) \_\_\_\_\_ (State) \_\_\_\_\_ (Zip Code).

This statement is submitted in order to obtain a Drug Enforcement Administration registration number.

I understand that if a DEA registration number is issued, the pharmacy may acquire

controlled substances but may not dispense them until a pharmacy permit or license is issued by the State board of pharmacy or licensing agency.

I understand that if any information is false, the Administration may immediately suspend the registration for this store and commence proceedings to revoke under 21 U.S.C. 824(a) because of the danger to public health and safety. I further understand that any false information contained in this affidavit may subject me personally to prosecution under 21 U.S.C. 843, the penalties for conviction of which include imprisonment for up to 4 years, a fine of not more than \$30,000 or both.

Signature (Person who signs Application for Registration)

State of \_\_\_\_\_

County of \_\_\_\_\_

Subscribed to and sworn before me this \_\_\_\_\_ day of \_\_\_\_\_, 19\_\_\_\_.

#### Notary Public

(c) The Administrator shall follow the normal procedures for approving an application to verify the statements in the affidavit. If the statements prove to be false, the Administrator may revoke the registration on the basis of section 304(a)(1) of the Act (21 U.S.C. 824(a)(1)) and suspend the registration immediately by pending revocation on the basis of section 304(d) of the Act (21 U.S.C. 824(d)). At the same time, the Administrator may seize and place under seal all controlled substances possessed by the applicant under section 304(f) of the Act (21 U.S.C. 824(f)). Intentional misuse of the affidavit procedure may subject the applicant to prosecution for fraud under section 403(a)(4) of the Act (21 U.S.C. 843(a)(4)), and obtaining controlled substances under a registration fraudulently gotten may subject the applicant to prosecution under section 403(a)(3) of the Act (21 U.S.C. 843(a)(3)). The penalties for conviction of either offense include imprisonment for up to 4 years, a fine not exceeding \$30,000 or both.

#### § 1301.18 Research protocols.

(a) A protocol to conduct research with controlled substances listed in Schedule I shall be in the following form and contain the following information where applicable:

- (1) Investigator:
  - (i) Name, address, and DEA registration number; if any.
  - (ii) Institutional affiliation.
  - (iii) Qualifications, including a curriculum vitae and an appropriate bibliography (list of publications).
- (2) Research project:

(i) Title of project.

(ii) Statement of the purpose.

(iii) Name of the controlled substances or substances involved and the amount of each needed.

(iv) Description of the research to be conducted, including the number and species of research subjects, the dosage to be administered, the route and method of administration, and the duration of the project.

(v) Location where the research will be conducted.

(vi) Statement of the security provisions for storing the controlled substances (in accordance with § 1301.75) and for dispensing the controlled substances in order to prevent diversion.

(vii) If the investigator desires to manufacture or import any controlled substance listed in paragraph (a)(2)(iii) of this section, a statement of the quantity to be manufactured or imported and the sources of the chemicals to be used or the substance to be imported.

(3) Authority:

(i) Institutional approval.

(ii) Approval of a Human Research Committee for human studies.

(iii) Indication of an approved active Notice of Claimed Investigational Exemption for a New Drug (number).

(iv) Indication of an approved funded grant (number), if any.

(b) In the case of a clinical investigation with controlled substances listed in Schedule I, the applicant shall submit three copies of a Notice of Claimed Investigational Exemption for a New Drug (IND) together with a statement of the security provisions (as prescribed in paragraph (a)(2)(v) of this section for a research protocol) to, and have such submission approved by, the Food and Drug Administration as required in 21 U.S.C. 355(i) and § 130.3 of this title. Submission of this Notice and statement to the Food and Drug Administration shall be in lieu of a research protocol to the Administration as required in paragraph (a) of this section. The applicant, when applying for registration with the Administration, shall indicate that such notice has been submitted to the Food and Drug Administration by submitting to the Administration with his/her DEA Form 225 three copies of the following certificate:

I hereby certify that on \_\_\_\_\_ (Date), pursuant to 21 U.S.C. 355(i) and 21 CFR 130.3, I, \_\_\_\_\_ (Name and Address of IND Sponsor) submitted a Notice of Claimed Investigational Exemption for a New Drug (IND) to the Food and Drug Administration for:



(Name of Investigational Drug).  
(Date)

(Signature of Applicant).

(c) In the event that the registrant desires to increase the quantity of a controlled substance used for an approved research project, he/she shall submit a request to the Registration Unit, Drug Enforcement Administration, Post Office Box 28083, Central Station, Washington, DC 20005, by registered mail, return receipt requested. The request shall contain the following information: DEA registration number; name of the controlled substance or substances and the quantity of each authorized in the approved protocol; and the additional quantity of each desired. Upon return of the receipt, the registrant shall be authorized to purchase the additional quantity of the controlled substance or substances specified in the request. The Administration shall review the letter and forward it to the Food and Drug Administration together with the Administration comments. The Food and Drug Administration shall approve or deny the request as an amendment to the protocol and so notify the registrant. Approval of the letter by the Food and Drug Administration shall authorize the registrant to use the additional quantity of the controlled substance in the research project.

(d) In the event the registrant desires to conduct research beyond the variations provided in the registrant's approved protocol (excluding any increase in the quantity of the controlled substance requested for his/her research project as outlined in paragraph (c) of this section), he/she shall submit three copies of a supplemental protocol in accordance with paragraph (a) of this section describing the new research and omitting information in the supplemental protocol which has been stated in the original protocol. Supplemental protocols shall be processed and approved or denied in the same manner as original research protocols.

#### Exceptions To Registration and Fees

##### **§ 1301.21 Exemption from fees.**

(a) The Administrator shall exempt from payment of an application fee for registration or reregistration:

(1) Any hospital or other institution which is operated by an agency of the United States (including the U.S. Army, Navy, Marine Corps., Air Force, and Coast Guard), of any State, or any political subdivision or agency thereof.

(2) Any individual practitioner who is required to obtain an individual registration in order to carry out his or her duties as an official of an agency of the United States (including the U.S. Army, Navy, Marine Corps., Air Force, and Coast Guard), of any State, or any political subdivision or agency thereof.

(b) In order to claim exemption from payment of a registration or reregistration application fee, the registrant shall have completed the certification on the appropriate application form, wherein the registrant's superior (if the registrant is an individual) or officer (if the registrant is an agency) certifies to the status and address of the registrant and to the authority of the registrant to acquire, possess, or handle controlled substances.

(c) Exemption from payment of a registration or reregistration application fee does not relieve the registrant of any other requirements or duties prescribed by law.

##### **§ 1301.22 Exemption of agents and employees; affiliated practitioners.**

(a) The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his/her business or employment.

(b) An individual practitioner who is an agent or employee of another practitioner (other than a mid-level practitioner) registered to dispense controlled substances may, when acting in the normal course of business or employment, administer or dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he or she practices, under the registration of the employer or principal practitioner in lieu of being registered him/herself.

(c) An individual practitioner who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered him/herself, provided that:

(1) Such dispensing, administering or prescribing is done in the usual course of his/her professional practice;

(2) Such individual practitioner is authorized or permitted to do so by the jurisdiction in which he/she is practicing;

(3) The hospital or other institution by whom he/she is employed has verified that the individual practitioner is so permitted to dispense, administer, or prescribe drugs within the jurisdiction;

(4) Such individual practitioner is acting only within the scope of his/her employment in the hospital or institution;

(5) The hospital or other institution authorizes the individual practitioner to administer, dispense or prescribe under the hospital registration and designates a specific internal code number for each individual practitioner so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the institution's DEA registration number, preceded by a hyphen (e.g., APO 123456-10 or APO123456-A12); and

(6) A current list of internal codes and the corresponding individual practitioners is kept by the hospital or other institution and is made available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner.

##### **§ 1301.23 Exemption of certain military and other personnel.**

(a) The requirement of registration is waived for any official of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Public Health Service, or Bureau of Prisons who is authorized to prescribe, dispense, or administer, but not to procure or purchase, controlled substances in the course of his/her official duties. Such officials shall follow procedures set forth in part 1306 of this chapter regarding prescriptions, but shall state the branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and the service identification number of the issuing official in lieu of the registration number required on prescription forms. The service identification number for a Public Health Service employee is his/her Social Security identification number.

(b) The requirement of registration is waived for any official or agency of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, or Public Health Service who or which is authorized to import or export controlled substances in the course of his/her official duties.

(c) If any official exempted by this section also engages as a private individual in any activity or group of activities for which registration is required, such official shall obtain a registration for such private activities.

**§ 1301.24 Exemption of law enforcement officials.**

(a) The requirement of registration is waived for the following persons in the circumstances described in this section:

(1) Any officer or employee of the Administration, any officer of the U.S. Customs Service, any officer or employee of the United States Food and Drug Administration, and any other Federal officer who is lawfully engaged in the enforcement of any Federal law relating to controlled substances, drugs or customs, and is duly authorized to possess or to import or export controlled substances in the course of his/her official duties; and

(2) Any officer or employee of any State, or any political subdivision or agency thereof, who is engaged in the enforcement of any State or local law relating to controlled substances and is duly authorized to possess controlled substances in the course of his/her official duties.

(b) Any official exempted by this section may, when acting in the course of his/her official duties, procure any controlled substance in the course of an inspection, in accordance with § 1316.03(d) of this chapter, or in the course of any criminal investigation involving the person from whom the substance was procured, and may possess any controlled substance and distribute any such substance to any other official who is also exempted by this section and acting in the course of his/her official duties.

(c) In order to enable law enforcement agency laboratories, including laboratories of the Administration, to obtain and transfer controlled substances for use as standards in chemical analysis, such laboratories shall obtain annually a registration to conduct chemical analysis. Such laboratories shall be exempted from payment of a fee for registration. Laboratory personnel, when acting in the scope of their official duties, are deemed to be officials exempted by this section and within the activity described in section 515(d) of the Act (21 U.S.C. 885(d)). For purposes of this paragraph, laboratory activities shall not include field or other preliminary chemical tests by officials exempted by this section.

(d) In addition to the activities authorized under a registration to conduct chemical analysis pursuant to § 1301.13(e)(1)(ix), laboratories of the Administration shall be authorized to manufacture or import controlled substances for any lawful purpose, to distribute or export such substances to any person, and to import and export

such substances in emergencies without regard to the requirements of part 1312 of this chapter if a report concerning the importation or exportation is made to the Drug Operations Section of the Administration within 30 days of such importation or exportation.

**§ 1301.25 Registration regarding ocean vessels, aircraft, and other entities.**

(a) If acquired by and dispensed under the general supervision of a medical officer described in paragraph (b) of this section, or the master or first officer of the vessel under the circumstances described in paragraph (d) of this section, controlled substances may be held for stocking, be maintained in, and dispensed from medicine chests, first aid packets, or dispensaries:

(1) On board any vessel engaged in international trade or in trade between ports of the United States and any merchant vessel belonging to the U.S. Government;

(2) On board any aircraft operated by an air carrier under a certificate of permit issued pursuant to the Federal Aviation Act of 1958 (49 U.S.C. 1301); and

(3) In any other entity of fixed or transient location approved by the Administrator as appropriate for application of this section (e.g., emergency kits at field sites of an industrial firm).

(b) A medical officer shall be:

(1) Licensed in a state as a physician;

(2) Employed by the owner or operator of the vessel, aircraft or other entity; and

(3) Registered under the Act at either of the following locations:

(i) The principal office of the owner or operator of the vessel, aircraft or other entity or

(ii) At any other location provided that the name, address, registration number and expiration date as they appear on his/her Certificate of Registration (DEA Form 223) for this location are maintained for inspection at said principal office in a readily retrievable manner.

(c) A registered medical officer may serve as medical officer for more than one vessel, aircraft, or other entity under a single registration, unless he/she serves as medical officer for more than one owner or operator, in which case he/she shall either maintain a separate registration at the location of the principal office of each such owner or operator or utilize one or more registrations pursuant to paragraph (b)(3)(ii) of this section.

(d) If no medical officer is employed by the owner or operator of a vessel, or

in the event such medical officer is not accessible and the acquisition of controlled substances is required, the master or first officer of the vessel, who shall not be registered under the Act, may purchase controlled substances from a registered manufacturer or distributor, or from an authorized pharmacy as described in paragraph (f) of this section, by following the procedure outlined below:

(1) The master or first officer of the vessel must personally appear at the vendor's place of business, present proper identification (e.g., Seaman's photographic identification card) and a written requisition for the controlled substances.

(2) The written requisition must be on the vessel's official stationery or purchase order form and must include the name and address of the vendor, the name of the controlled substance, description of the controlled substance (dosage form, strength and number or volume per container) number of containers ordered, the name of the vessel, the vessel's official number and country of registry, the owner or operator of the vessel, the port at which the vessel is located, signature of the vessel's officer who is ordering the controlled substances and the date of the requisition.

(3) The vendor may, after verifying the identification of the vessel's officer requisitioning the controlled substances, deliver the control substances to that officer. The transaction shall be documented, in triplicate, on a record of sale in a format similar to that outlined in paragraph (d)(4) of this section. The vessel's requisition shall be attached to copy 1 of the record of sale and filed with the controlled substances records of the vendor, copy 2 of the record of sale shall be furnished to the officer of the vessel and retained aboard the vessel, copy 3 of the record of sale shall be forwarded to the nearest DEA Division Office within 15 days after the end of the month in which the sale is made.

(4) The vendor's record of sale should be similar to, and must include all the information contained in, the below listed format.

Sale of Controlled Substances to Vessels  
(Name of registrant)

(Address of registrant)

(DEA registration number)

\* \* \* TABLE START \* \* \*

Line No.	Number of packages ordered	Size of packages	Name of product	Packages distributed	Date distributed
1 .....	.....	.....	.....	.....	.....
2 .....	.....	.....	.....	.....	.....
3 .....	.....	.....	.....	.....	.....

FOOTNOTE: Line numbers may be continued according to needs of the vendor.

\*\*\* TABLE END \*\*\*

Number of lines completed

Name of vessel

Vessel's official number

Vessel's country of registry

Owner or operator of the vessel

Name and title of vessel's officer who presented the requisition

Signature of vessel's officer who presented the requisition

(e) Any medical officer described in paragraph (b) of this section shall, in addition to complying with all requirements and duties prescribed for registrants generally, prepare an annual report as of the date on which his/her registration expires, which shall give in detail an accounting for each vessel, aircraft, or other entity, and a summary accounting for all vessels, aircraft, or other entities under his/her supervision for all controlled substances purchased, dispensed or disposed of during the year. The medical officer shall maintain this report with other records required to be kept under the Act and, upon request, deliver a copy of the report to the Administration. The medical officer need not be present when controlled substances are dispensed, if the person who actually dispensed the controlled substances is responsible to the medical officer to justify his/her actions.

(f) Any registered pharmacy which wishes to distribute controlled substances pursuant to this section shall be authorized to do so, provided that:

(1) The registered pharmacy notifies the nearest Division Office of the Administration of its intention to so distribute controlled substances prior to the initiation of such activity. This notification shall be by registered mail and shall contain the name, address, and registration number of the pharmacy as well as the date upon which such activity will commence; and

(2) Such activity is authorized by state law; and

(3) The total number of dosage units of all controlled substances distributed by the pharmacy during any calendar

year in which the pharmacy is registered to dispense does not exceed the limitations imposed upon such distribution by § 1307.11(a) (4) and (b) of this chapter.

(g) Owners or operators of vessels, aircraft, or other entities described in this section shall not be deemed to possess or dispense any controlled substance acquired, stored and dispensed in accordance with this section. Additionally, owners or operators of vessels, aircraft, or other entities described in this section or in Article 32 of the Single Convention on Narcotic Drugs, 1961, or in Article 14 of the Convention on Psychotropic Substances, 1971, shall not be deemed to import or export any controlled substances purchased and stored in accordance with that section or applicable article.

(h) The Master of a vessel shall prepare a report for each calendar year which shall give in detail an accounting for all controlled substances purchased, dispensed, or disposed of during the year. The Master shall file this report with the medical officer employed by the owner or operator of his/her vessel, if any, or, if not, he/she shall maintain this report with other records required to be kept under the Act and, upon request, deliver a copy of the report to the Administration.

(i) Controlled substances acquired and possessed in accordance with this section shall not be distributed to persons not under the general supervision of the medical officer employed by the owner or operator of the vessel, aircraft, or other entity, except in accordance with § 1307.21 of this chapter.

#### **§ 1301.26 Exemptions from import or export requirements for personal medical use.**

Any individual who has in his/her possession a controlled substance listed in schedules II, III, IV, or V, which he/she has lawfully obtained for his/her personal medical use, or for administration to an animal accompanying him/her, may enter or depart the United States with such substance notwithstanding sections 1002–1005 of the Act (21 U.S.C. 952–955), providing the following conditions are met:

(a) The controlled substance is in the original container in which it was dispensed to the individual; and

(b) The individual makes a declaration to an appropriate official of the U.S. Customs Service stating:

(1) That the controlled substance is possessed for his/her personal use, or for an animal accompanying him/her; and

(2) The trade or chemical name and the symbol designating the schedule of the controlled substance if it appears on the container label, or, if such name does not appear on the label, the name and address of the pharmacy or practitioner who dispensed the substance and the prescription number, if any.

Action on Applications for Registration: Revocation or Suspension of Registration

#### **§ 1301.31 Administrative review generally.**

The Administrator may inspect, or cause to be inspected, the establishment of an applicant or registrant, pursuant to subpart A of part 1316 of this chapter. The Administrator shall review, the application for registration and other information gathered by the Administrator regarding an applicant in order to determine whether the applicable standards of section 303 of the Act (21 U.S.C. 823) or section 1008 (21 U.S.C. 958) have been met by the applicant.

#### **§ 1301.32 Action on applications for research in Schedule I substances.**

(a) In the case of an application for registration to conduct research with controlled substances listed in Schedule I, the Administrator shall process the application and protocol and forward a copy of each to the Secretary within 7 days after receipt. The Secretary shall determine the qualifications and competency of the applicant, as well as the merits of the protocol (and shall notify the Administrator of his/her determination) within 21 days after receipt of the application and complete protocol, except that in the case of a clinical investigation, the Secretary shall have 30 days to make such determination and notify the Administrator. The Secretary, in determining the merits of the protocol,

shall consult with the Administrator as to effective procedures to safeguard adequately against diversion of such controlled substances from legitimate medical or scientific use.

(b) An applicant whose protocol is defective shall be notified by the Secretary within 21 days after receipt of such protocol from the Administrator (or in the case of a clinical investigation within 30 days), and he/she shall be requested to correct the existing defects before consideration shall be given to his/her submission.

(c) If the Secretary determines the applicant qualified and competent and the research protocol meritorious, he/she shall notify the Administrator in writing of such determination. The Administrator shall issue a certificate of registration within 10 days after receipt of this notice, unless he/she determines that the certificate of registration should be denied on a ground specified in section 304(a) of the Act (21 U.S.C. 824(a)). In the case of a supplemental protocol, a replacement certificate of registration shall be issued by the Administrator.

(d) If the Secretary determines that the protocol is not meritorious and/or the applicant is not qualified or competent, he/she shall notify the Administrator in writing setting forth the reasons for such determination. If the Administrator determines that grounds exist for the denial of the application, he/she shall within 10 days issue an order to show cause pursuant to § 1301.37 and, if requested by the applicant, hold a hearing on the application pursuant to § 1301.41. If the grounds for denial of the application include a determination by the Secretary, the Secretary or his duly authorized agent shall furnish testimony and documents pertaining to his determination at such hearing.

(e) Supplemental protocols will be processed in the same manner as original research protocols. If the processing of an application or research protocol is delayed beyond the time limits imposed by this section, the applicant shall be so notified in writing.

**§ 1301.33 Application for bulk manufacture of Schedule I and II substances.**

(a) In the case of an application for registration or reregistration to manufacture in bulk a basic class of controlled substance listed in Schedule I or II, the Administrator shall, upon the filing of such application, publish in the Federal Register a notice naming the applicant and stating that such applicant has applied to be registered as a bulk manufacturer of a basic class of narcotic or nonnarcotic controlled substance, which class shall be

identified. A copy of said notice shall be mailed simultaneously to each person registered as a bulk manufacturer of that basic class and to any other applicant therefor. Any such person may, within 60 days from the date of publication of the notice in the Federal Register, file with the Administrator written comments on or objections to the issuance of the proposed registration.

(b) In order to provide adequate competition, the Administrator shall not be required to limit the number of manufacturers in any basic class to a number less than that consistent with maintenance of effective controls against diversion solely because a smaller number is capable of producing an adequate and uninterrupted supply.

(c) This section shall not apply to the manufacture of basic classes of controlled substances listed in Schedules I or II as an incident to research or chemical analysis as authorized in § 01.13(e)(1).

**§ 1301.34 Application for importation of Schedule I and II substances.**

(a) In the case of an application for registration or reregistration to import a controlled substance listed in Schedule I or II, under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)), the Administrator shall, upon the filing of such application, publish in the Federal Register a notice naming the applicant and stating that such applicant has applied to be registered as an importer of a Schedule I or II controlled substance, which substance shall be identified. A copy of said notice shall be mailed simultaneously to each person registered as a bulk manufacturer of that controlled substance and to any other applicant therefor. Any such person may, within 30 days from the date of publication of the notice in the Federal Register, file written comments on or objections to the issuance of the proposed registration, and may, at the same time, file a written request for a hearing on the application pursuant to § 1301.43. If a hearing is requested, the Administrator shall hold a hearing on the application in accordance with § 1301.41. Notice of the hearing shall be published in the Federal Register, and shall be mailed simultaneously to the applicant and to all persons to whom notice of the application was mailed. Any such person may participate in the hearing by filing a notice of appearance in accordance with § 1301.43 of this chapter. Notice of the hearing shall contain a summary of all comments and objections filed regarding the application and shall state the time and place for the hearing, which shall not be

less than 30 days after the date of publication of such notice in the Federal Register. A hearing pursuant to this section may be consolidated with a hearing held pursuant to §§ 1301.35 or 1301.36 of this part.

(b) The Administrator shall register an applicant to import a controlled substance listed in Schedule I or II if he/she determines that such registration is consistent with the public interest and with U.S. obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) Maintenance of effective controls against diversion of particular controlled substances and any controlled substance in Schedule I or II compounded therefrom into other than legitimate medical, scientific research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) Compliance with applicable State and local law;

(3) Promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) Prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) Past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion;

(6) That the applicant will be permitted to import only:

(i) Such amounts of crude opium, poppy straw, concentrate of poppy straw, and coca leaves as the Administrator finds to be necessary to provide for medical, scientific, or other legitimate purposes; or

(ii) Such amounts of any controlled substances listed in Schedule I or II as the Administrator shall find to be necessary to provide for the medical, scientific, or other legitimate needs of the United States during an emergency in which domestic supplies of such substances are found by the Administrator to be inadequate; or

(iii) Such amounts of any controlled substance listed in Schedule I or II as the Administrator shall find to be necessary to provide for the medical, scientific, or other legitimate needs of the United States in any case in which

the Administrator finds that competition among domestic manufacturers of the controlled substance is inadequate and will not be rendered adequate by the registration of additional manufacturers under section 303 of the Act (21 U.S.C. 823); or

(iv) Such limited quantities of any controlled substance listed in Schedule I or II as the Administrator shall find to be necessary for scientific, analytical or research uses; and

(7) Such other factors as may be relevant to and consistent with the public health and safety.

(c) In determining whether the applicant can and will maintain effective controls against diversion within the meaning of paragraph (b) of this section, the Administrator shall consider among other factors:

(1) Compliance with the security requirements set forth in §§ 1301.71–1301.76 and

(2) Employment of security procedures to guard against in-transit losses within and without the jurisdiction of the United States.

(d) In determining whether competition among the domestic manufacturers of a controlled substance is adequate within the meaning of paragraphs (b)(1) and (b)(6)(iii) of this section, as well as section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)), the Administrator shall consider:

(1) The extent of price rigidity in the light of changes in:

- (i) Raw materials and other costs and
- (ii) Conditions of supply and demand;

(2) The extent of service and quality competition among the domestic manufacturers for shares of the domestic market including:

- (i) Shifts in market shares and
- (ii) Shifts in individual customers

among domestic manufacturers;

(3) The existence of substantial differentials between domestic prices and the higher of prices generally prevailing in foreign markets or the prices at which the applicant for registration to import is committed to undertake to provide such products in the domestic market in conformity with the Act. In determining the existence of substantial differentials hereunder, appropriate consideration should be given to any additional costs imposed on domestic manufacturers by the requirements of the Act and such other cost-related and other factors as the Administrator may deem relevant. In no event shall an importer's offering prices in the United States be considered if they are lower than those prevailing in the foreign market or markets from which the importer is obtaining his/her supply;

(4) The existence of competitive restraints imposed upon domestic manufacturers by governmental regulations; and

(5) Such other factors as may be relevant to the determinations required under this paragraph.

(e) In considering the scope of the domestic market, consideration shall be given to substitute products which are reasonably interchangeable in terms of price, quality and use.

(f) The fact that the number of existing manufacturers is small shall not demonstrate, in and of itself, that adequate competition among them does not exist.

#### **§ 1301.35 Certificate of registration; denial of registration.**

(a) The Administrator shall issue a Certificate of Registration (DEA Form 223) to an applicant if the issuance of registration or reregistration is required under the applicable provisions of sections 303 or 1008 of the Act (21 U.S.C. 823 and 958). In the event that the issuance of registration or reregistration is not required, the Administrator shall deny the application. Before denying any application, the Administrator shall issue an order to show cause pursuant to § 1301.37 and, if requested by the applicant, shall hold a hearing on the application pursuant to § 1301.41.

(b) If a hearing is requested by an applicant for registration or reregistration to manufacture in bulk a basic class of controlled substance listed in Schedule I or II, notice that a hearing has been requested shall be published in the Federal Register and shall be mailed simultaneously to the applicant and to all persons to whom notice of the application was mailed. Any person entitled to file comments or objections to the issuance of the proposed registration pursuant to § 1301.33(a) may participate in the hearing by filing notice of appearance in accordance with § 1301.43. Such persons shall have 30 days to file a notice of appearance after the date of publication of the notice of a request for a hearing in the Federal Register.

(c) The Certificate of Registration (DEA Form 223) shall contain the name, address, and registration number of the registrant, the activity authorized by the registration, the schedules and/or Administration Controlled Substances Code Number (as set forth in part 1308 of this chapter) of the controlled substances which the registrant is authorized to handle, the amount of fee paid (or exemption), and the expiration date of the registration. The registrant shall maintain the certificate of

registration at the registered location in a readily retrievable manner and shall permit inspection of the certificate by any official, agent or employee of the Administration or of any Federal, State, or local agency engaged in enforcement of laws relating to controlled substances.

#### **§ 1301.36 Suspension or revocation of registration; suspension of registration pending final order; extension of registration pending final order.**

(a) For any registration issued under section 303 of the Act (21 U.S.C. 823), the Administrator may:

(1) Suspend the registration pursuant to section 304(a) of the Act (21 U.S.C. 824(a)) for any period of time.

(2) Revoke the registration pursuant to section 304(a) of the Act (21 U.S.C. 824(a)).

(b) For any registration issued under section 1008 of the Act (21 U.S.C. 958), the Administrator may:

(1) Suspend the registration pursuant to section 1008(d) of the Act (21 U.S.C. 958(d)) for any period of time.

(2) Revoke the registration pursuant to section 1008(d) of the Act (21 U.S.C. 958(d)) if he/she determines that such registration is inconsistent with the public interest as defined in section 1008 or with the United States obligations under international treaties, conventions, or protocols in effect on October 12, 1984.

(c) The Administrator may limit the revocation or suspension of a registration to the particular controlled substance, or substances, with respect to which grounds for revocation or suspension exist.

(d) Before revoking or suspending any registration, the Administrator shall issue an order to show cause pursuant to § 1301.37 and, if requested by the registrant, shall hold a hearing pursuant to § 1301.41.

(e) The Administrator may suspend any registration simultaneously with or at any time subsequent to the service upon the registrant of an order to show cause why such registration should not be revoked or suspended, in any case where he/she finds that there is an imminent danger to the public health or safety. If the Administrator so suspends, he/she shall serve with the order to show cause pursuant to § 1301.37 an order of immediate suspension which shall contain a statement of his findings regarding the danger to public health or safety.

(f) Upon service of the order of the Administrator suspending or revoking registration, the registrant shall immediately deliver his/her Certificate of Registration, any order forms, and

any import or export permits in his/her possession to the nearest office of the Administration. The suspension or revocation of a registration shall suspend or revoke any individual manufacturing or procurement quota fixed for the registrant pursuant to part 1303 of this chapter and any import or export permits issued to the registrant pursuant to part 1312 of this chapter. Also, upon service of the order of the Administrator revoking or suspending registration, the registrant shall, as instructed by the Administrator:

(1) Deliver all controlled substances in his/her possession to the nearest office of the Administration or to authorized agents of the Administration; or

(2) Place all controlled substances in his/her possession under seal as described in sections 304(f) or 1008(d)(6) of the Act (21 U.S.C. 824(f) or 958(d)(6)).

(g) In the event that revocation or suspension is limited to a particular controlled substance or substances, the registrant shall be given a new Certificate of Registration for all substances not affected by such revocation or suspension; no fee shall be required to be paid for the new Certificate of Registration. The registrant shall deliver the old Certificate of Registration and, if appropriate, any order forms in his/her possession to the nearest office of the Administration. The suspension or revocation of a registration, when limited to a particular basic class or classes of controlled substances, shall suspend or revoke any individual manufacturing or procurement quota fixed for the registrant for such class or classes pursuant to part 1303 of this chapter and any import or export permits issued to the registrant for such class or classes pursuant to part 1312 of this chapter. Also, upon service of the order of the Administrator revoking or suspending registration, the registrant shall, as instructed by the Administrator:

(1) Deliver to the nearest office of the Administration or to authorized agents of the Administration all of the particular controlled substance or substances affected by the revocation or suspension which are in his/her possession; or

(2) Place all of such substances under seal as described in sections 304(f) or 958(d)(6) of the Act (21 U.S.C. 824(f) or 958(d)(6)).

(h) Any suspension shall continue in effect until the conclusion of all proceedings upon the revocation or suspension, including any judicial review thereof, unless sooner withdrawn by the Administrator or

dissolved by a court of competent jurisdiction. Any registrant whose registration is suspended under paragraph (e) of this section may request a hearing on the revocation or suspension of his/her registration at a time earlier than specified in the order to show cause pursuant to § 1301.37, which request shall be granted by the Administrator, who shall fix a date for such hearing as early as reasonably possible.

(i) In the event that an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration at least 45 days before the date on which the existing registration is due to expire, and the Administrator has issued no order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the Administrator so issues his/her order. The Administrator may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for reregistration at least 45 days before expiration of the existing registration, with or without request by the registrant, if the Administrator finds that such extension is not inconsistent with the public health and safety.

#### **§ 1301.37 Order to show cause.**

(a) If, upon examination of the application for registration from any applicant and other information gathered by the Administration regarding the applicant, the Administrator is unable to make the determinations required by the applicable provisions of section 303 and/or section 1008 of the Act (21 U.S.C. 823 and 958) to register the applicant, the Administrator shall serve upon the applicant an order to show cause why the registration should not be denied.

(b) If, upon information gathered by the Administration regarding any registrant, the Administrator determines that the registration of such registrant is subject to suspension or revocation pursuant to section 304 or section 1008 of the Act (21 U.S.C. 824 and 958), the Administrator shall serve upon the registrant an order to show cause why the registration should not be revoked or suspended.

(c) The order to show cause shall call upon the applicant or registrant to appear before the Administrator at a time and place stated in the order, which shall not be less than 30 days

after the date of receipt of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.

(d) Upon receipt of an order to show cause, the applicant or registrant must, if he/she desires a hearing, file a request for a hearing pursuant to § 1301.43. If a hearing is requested, the Administrator shall hold a hearing at the time and place stated in the order, pursuant to § 1301.41.

(e) When authorized by the Administrator, any agent of the Administration may serve the order to show cause.

#### **Hearings**

##### **§ 1301.41 Hearings generally.**

(a) In any case where the Administrator shall hold a hearing on any registration or application therefor, the procedures for such hearing shall be governed generally by the adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by §§ 303, 304, and 1008 of the Act (21 U.S.C. 823–824 and 958), by §§ 1301.42–1301.46 of this part, and by the procedures for administrative hearings under the Act set forth in §§ 1316.41–1316.67 of this chapter.

(b) Any hearing under this part shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under the Act or any other law of the United States.

##### **§ 1301.42 Purpose of hearing.**

If requested by a person entitled to a hearing, the Administrator shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the denial, revocation, or suspension of any registration, and the granting of any application for registration to manufacture in bulk a basic class of controlled substance listed in Schedule I or II. Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.

##### **§ 1301.43 Request for hearing or appearance; waiver.**

(a) Any person entitled to a hearing pursuant to §§ 1301.32 or 1301.34–1301.36 and desiring a hearing shall, within 30 days after the date of receipt of the order to show cause (or the date of publication of notice of the application for registration in the Federal Register in the case of

§ 1301.34), file with the Administrator a written request for a hearing in the form prescribed in § 1316.47 of this chapter.

(b) Any person entitled to participate in a hearing pursuant to § 1301.34 or § 1301.35(b) and desiring to do so shall, within 30 days of the date of publication of notice of the request for a hearing in the Federal Register, file with the Administrator a written notice of intent to participate in such hearing in the form prescribed in § 1316.48 of this chapter. Any person filing a request for a hearing need not also file a notice of appearance.

(c) Any person entitled to a hearing or to participate in a hearing pursuant to § 1301.32 or §§ 1301.34–1301.36 may, within the period permitted for filing a request for a hearing or a notice of appearance, file with the Administrator a waiver of an opportunity for a hearing or to participate in a hearing, together with a written statement regarding such person's position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

(d) If any person entitled to a hearing or to participate in a hearing pursuant to §§ 1301.32 or 1301.34–1301.36 fails to file a request for a hearing or a notice of appearance, or if such person so files and fails to appear at the hearing, such person shall be deemed to have waived the opportunity for a hearing or to participate in the hearing, unless such person shows good cause for such failure.

(e) If all persons entitled to a hearing or to participate in a hearing waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Administrator may cancel the hearing, if scheduled, and issue his/her final order pursuant to § 1301.46 without a hearing.

#### **§ 1301.44 Burden of proof.**

(a) At any hearing on an application to manufacture any controlled substance listed in Schedule I or II, the applicant shall have the burden of proving that the requirements for such registration pursuant to section 303(a) of the Act (21 U.S.C. 823(a)) are satisfied. Any other person participating in the hearing pursuant to § 1301.35(b) shall have the burden of proving any propositions of fact or law asserted by such person in the hearing.

(b) At any hearing on the granting or denial of an applicant to be registered to conduct a narcotic treatment program or as a compounder, the applicant shall

have the burden of proving that the requirements for each registration pursuant to section 303(g) of the Act (21 U.S.C. 823(g)) are satisfied.

(c) At any hearing on the granting or denial of an application to be registered to import or export any controlled substance listed in Schedule I or II, the applicant shall have the burden of proving that the requirements for such registration pursuant to sections 1008 (a) and (d) of the Act (21 U.S.C. 958 (a) and (d)) are satisfied. Any other person participating in the hearing pursuant to § 1301.34 shall have the burden of proving any propositions of fact or law asserted by him/her in the hearings.

(d) At any other hearing for the denial of a registration, the Administration shall have the burden of proving that the requirements for such registration pursuant to section 303 or section 1008 (c) and (d) of the Act (21 U.S.C. 823 or 958 (c) and (d)) are not satisfied.

(e) At any hearing for the revocation or suspension of a registration, the Administration shall have the burden of proving that the requirements for such revocation or suspension pursuant to section 304(a) or section 1008(d) of the Act (21 U.S.C. 824(a) or 958(d)) are satisfied.

#### **§ 1301.45 Time and place of hearing.**

The hearing will commence at the place and time designated in the order to show cause or notice of hearing published in the Federal Register (unless expedited pursuant to § 1301.36(h)) but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

#### **§ 1301.46 Final order.**

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall issue his/her order on the granting, denial, revocation, or suspension of registration. In the event that an application for registration to manufacture in bulk a basic class of any controlled substance listed in Schedule I or II is granted, or any application for registration is denied, or any registration is revoked or suspended, the order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. The Administrator shall serve one copy of his/her order upon each party in the hearing.

Modification, Transfer and Termination of Registration

#### **§ 1301.51 Modification in registration.**

Any registrant may apply to modify his/her registration to authorize the handling of additional controlled substances or to change his/her name or address, by submitting a letter of request to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005. The letter shall contain the registrant's name, address, and registration number as printed on the certificate of registration, and the substances and/or schedules to be added to his/her registration or the new name or address and shall be signed in accordance with § 1301.13(j). If the registrant is seeking to handle additional controlled substances listed in Schedule I for the purpose of research or instructional activities, he/she shall attach three copies of a research protocol describing each research project involving the additional substances, or two copies of a statement describing the nature, extent, and duration of such instructional activities, as appropriate. No fee shall be required to be paid for the modification. The request for modification shall be handled in the same manner as an application for registration. If the modification in registration is approved, the Administrator shall issue a new certificate of registration (DEA Form 223) to the registrant, who shall maintain it with the old certificate of registration until expiration.

#### **§ 1301.52 Termination of registration; transfer of registration; distribution upon discontinuance of business.**

(a) Except as provided in paragraph (b) of this section, the registration of any person shall terminate if and when such person dies, ceases legal existence, or discontinues business or professional practice. Any registrant who ceases legal existence or discontinues business or professional practice shall notify the Administrator promptly of such fact.

(b) No registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the Administration may specifically designate and then only pursuant to written consent. Any person seeking authority to transfer a registration shall submit a written request, providing full details regarding the proposed transfer of registration, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration,

Department of Justice, Washington, DC 20537.

(c) Any registrant desiring to discontinue business activities altogether or with respect to controlled substances (without transferring such business activities to another person) shall return for cancellation his/her certificate of registration, and any unexecuted order forms in his/her possession, to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005. Any controlled substances in his/her possession may be disposed of in accordance with § 1307.21 of this chapter.

(d) Any registrant desiring to discontinue business activities altogether or with respect to controlled substance (by transferring such business activities to another person) shall submit in person or by registered or certified mail, return receipt requested, to the Special Agent in Charge in his/her area, at least 14 days in advance of the date of the proposed transfer (unless the Special Agent in Charge waives this time limitation in individual instances), the following information:

(1) The name, address, registration number, and authorized business activity of the registrant discontinuing the business (registrant-transferor);

(2) The name, address, registration number, and authorized business activity of the person acquiring the business (registrant-transferee);

(3) Whether the business activities will be continued at the location registered by the person discontinuing business, or moved to another location (if the latter, the address of the new location should be listed);

(4) Whether the registrant-transferor has a quota to manufacture or procure any controlled substance listed in Schedule I or II (if so, the basic class or class of the substance should be indicated); and

(5) The date on which the transfer of controlled substances will occur.

(e) Unless the registrant-transferor is informed by the Special Agent in Charge, before the date on which the transfer was stated to occur, that the transfer may not occur, the registrant-transferor may distribute (without being registered to distribute) controlled substances in his/her possession to the registrant-transferee in accordance with the following:

(1) On the date of transfer of the controlled substances, a complete inventory of all controlled substances being transferred shall be taken in accordance with § 1304.11 of this chapter. This inventory shall serve as

the final inventory of the registrant-transferor and the initial inventory of the registrant-transferee, and a copy of the inventory shall be included in the records of each person. It shall not be necessary to file a copy of the inventory with the Administration unless requested by the Special Agent in Charge. Transfers of any substances listed in Schedule I or II shall require the use of order forms in accordance with part 1305 of this chapter.

(2) On the date of transfer of the controlled substances, all records required to be kept by the registrant-transferor with reference to the controlled substances being transferred, under part 1304 of this chapter, shall be transferred to the registrant-transferee. Responsibility for the accuracy of records prior to the date of transfer remains with the transferor, but responsibility for custody and maintenance shall be upon the transferee.

(3) In the case of registrants required to make reports pursuant to part 1304 of this chapter, a report marked "Final" will be prepared and submitted by the registrant-transferor showing the disposition of all the controlled substances for which a report is required; no additional report will be required from him, if no further transactions involving controlled substances are consummated by him. The initial report of the registrant-transferee shall account for transactions beginning with the day next succeeding the date of discontinuance or transfer of business by the transferor-registrant and the substances transferred to him shall be reported as receipts in his/her initial report.

#### **§ 1301.75 Physical security controls for practitioners.**

\* \* \* \* \*

(b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

\* \* \* \* \*

6. Section 1301.76 is proposed to be amended by revising paragraph (c) to read as follows:

#### **§ 1301.76 Other security controls for practitioners.**

\* \* \* \* \*

(c) Whenever the registrant distributes a controlled substance (without being registered as a distributor, as permitted

in § 1301.13(e)(1) and/or §§ 1307.11–1307.12) he/she shall comply with the requirements imposed on nonpractitioners in § 1301.74 (a), (b), and (e).

#### **§ 1301.72 [Amended]**

7. In 21 CFR 1301.72(b)(4)(i)(b) remove the word "lay" and add, in its place, the word "lag".

#### **PART 1302—[AMENDED]**

1. The authority citation for part 1302 continues to read as follows:

Authority: 21 U.S.C. 821, 825, 871(b), 958 (e).

2. Section 1302.02 is proposed to be revised to read as follows:

#### **§ 1302.02 Definitions.**

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or Part 1300 of this chapter.

3. Section 1302.04 is proposed to be revised to read as follows:

#### **§ 1302.04 Location and size of symbol on label and labeling.**

The symbol shall be prominently located on the label or the labeling of the commercial container and/or the panel of the commercial container normally displayed to dispensers of any controlled substance. The symbol on labels shall be clear and large enough to afford easy identification of the schedule of the controlled substance upon inspection without removal from the dispenser's shelf. The symbol on all other labeling shall be clear and large enough to afford prompt identification of the controlled substance upon inspection of the labeling.

#### **§ 1302.05 [Removed]**

4. Section 1302.05 is proposed to be removed.

5. Section 1302.06 is proposed to be redesignated as Section 1302.05 and revised to read as follows:

#### **§ 1302.05 Effective dates of labeling requirements.**

All labels on commercial containers of, and all labeling of, a controlled substance which either is transferred to another schedule or is added to any schedule shall comply with the requirements of § 1302.03, on or before the effective date established in the final order for the transfer or addition.

6. Section 1302.07 is proposed to be redesignated as § 1302.06 and revised to read as follows:

#### **§ 1302.06 Sealing of controlled substances.**

On each bottle, multiple dose vial, or other commercial container of any



controlled substance, there shall be securely affixed to the stopper, cap, lid, covering, or wrapper or such container a seal to disclose upon inspection any tampering or opening of the container.

7. Section 1302.08 is proposed to be redesignated as § 1302.07, and revised to read as follows:

**§ 1302.07 Labeling and packaging requirements for imported and exported substances.**

(a) The symbol requirements of §§ 1302.03–1302.05 apply to every commercial container containing, and to all labeling of, controlled substances imported into the jurisdiction of and/or the customs territory of the United States.

(b) The symbol requirements of §§ 1302.03–1302.05 do not apply to any commercial containers containing, or any labeling of, a controlled substance intended for export from the jurisdiction of the United States.

(c) The sealing requirements of § 1302.06 apply to every bottle, multiple dose vial, or other commercial container of any controlled substance listed in schedule I or II, or any narcotic controlled substance listed in schedule III or IV, imported into, exported from, or intended for export from, the jurisdiction of and/or the customs territory of the United States.

**PART 1303—[AMENDED]**

1. The authority citation for part 1303 continues to read as follows:

Authority: 21 U.S.C. 821, 826, 871(b).

2. Section 1303.02 is proposed to be revised to read as follows:

**§ 1303.02 Definitions.**

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

3. In addition to the proposed amendments set forth above, DEA is proposing to amend each section indicated in the left column by removing the words indicated in the middle column and adding the words in the right column:

Section	Remove	Add
1303.12(b) .....	(or BND) each place it appears.	
1303.12(b) .....	Drug Control Section .....	Drug & Chemical Evaluation Section.
1303.12(d) .....	Drug Control Section .....	Drug & Chemical Evaluation Section.
1303.12(e)(1) .....	substance .....	substance.
1303.12(e)(3) .....	1301.22(b) .....	1301.13.
1303.21(a) .....	1301.45 and 1301.46 .....	1301.36.
1303.22 .....	(or BND) each place it appears.	
1303.22 .....	Drug Control Section .....	Drug & Chemical Evaluation Section.
1303.26 .....	1301.45 or 1301.46 .....	1301.36.
1303.27 .....	Drug Control Section .....	Drug & Chemical Evaluation Section.
1303.32(b) .....	1301.45 or 1301.46 .....	1301.36.
1303.35(a) .....	aggregate .....	aggregate.

**PART 1304—[AMENDED]**

1. The authority citation for part 1304 is proposed to be corrected to read as follows:

Authority: 21 U.S.C. 821, 827, 871(b), 958(e), 965, unless otherwise noted.

2. Section 1304.02 is proposed to be revised to read as follows:

**§ 1304.02 Definitions.**

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

3. Section 1304.03 is proposed to be amended by removing paragraphs (g) and (h), and revising paragraph (f) to read as follows:

**§ 1304.03 Persons required to keep records and file reports.**

\* \* \* \* \*

(f) Registered persons using any controlled substances while conducting preclinical research, in teaching at a registered establishment which maintains records with respect to such substances or conducting research in conformity with an exemption granted under section 505(i) or 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i) or 360b(j)) at a

registered establishment which maintains records in accordance with either of those sections are not required to keep records if he/she notifies the Administration of the name, address, and registration number of the establishment maintaining such records. This notification shall be given at the time the person applies for registration or reregistration and shall be made in the form of an attachment to the application, which shall be filed with the application.

4. Section 1304.04 is proposed to be amended by removing “executed” in paragraph (a) and by adding “executed” and by revising paragraphs (e) and (h) to read as follows:

**§ 1304.04 Maintenance of records and inventories.**

\* \* \* \* \*

(e) All central recordkeeping permits previously issued by the Administration expired September 30, 1980.

\* \* \* \* \*

(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the

pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file; and

(2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy, and prescriptions for such substances shall be maintained either in a separate prescription file for controlled substances listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter “C” no less than 1-inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for non-controlled substances. However, if a pharmacy employs an ADP system or other electronic recordkeeping system for prescriptions which permits

identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

5. Section 1304.11 is proposed to be revised to read as follows:

**§ 1304.11 Inventory requirements.**

(a) *General requirements.* Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

(b) *Initial inventory date.* Every person required to keep records, shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.

(c) *Biennial inventory date.* After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on the day of the year on which the initial inventory was taken or on any other fixed date which does not vary by more than 6 months from the biennial date that would otherwise

apply. If the registrant elects to take the biennial inventory on another fixed date, he/she shall notify the Administration of this election and of the date on which the biennial inventory will be taken.

(d) *Inventory date for newly controlled substances.* On the effective date of a rule by the Administrator pursuant to §§ 1308.45, 1308.46, or § 1308.47 of this chapter adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter, such substance shall be included in each inventory made by the registrant pursuant to paragraph (c) of this section.

(e) *Inventories of manufacturers, distributors, dispensers, researchers, importers, exporters and chemical analysts.* Each person registered or authorized (by §§ 1301.13 or §§ 1307.11–1307.13 of this chapter) to manufacture, distribute, dispense, import, export, conduct research or chemical analysis with controlled substances and required to keep records pursuant to § 1304.03 shall include in the inventory the information listed below.

(1) *Inventories of manufacturers.* Each person registered or authorized to manufacture controlled substances shall include the following information in the inventory:

(i) For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or non-controlled substances in finished form, the inventory shall include:

(A) The name of the substance and  
(B) the total quantity of the substance to the nearest metric unit weight consistent with unit size.

(ii) For each controlled substance in the process of manufacture on the inventory date, the inventory shall include:

(A) The name of the substance;  
(B) the quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number;  
(C) the physical form which the substance is to take upon completion of the manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per

fluid ounce or milliliter) and the number or volume thereof.

(iii) For each controlled substance in finished form the inventory shall include:

(A) The name of the substance;  
(B) each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);  
(C) the number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and  
(D) the number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials).

(iv) For each controlled substance not included in paragraphs (e)(1) (i), (ii) or (iii) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings) the inventories shall include:

(A) The name of the substance;  
(B) the total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and  
(C) the reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

(2) *Inventories of distributors.* Each person registered or authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section.

(3) *Inventories of dispensers and researchers.* Each person registered or authorized to dispense or conduct research with controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser shall do as follows:

(i) If the substance is listed in Schedule I or II, make an exact count or measure of the contents or  
(ii) if the substance is listed in Schedule III, IV or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.

(4) *Inventories of importers and exporters.* Each person registered or

authorized to import or export controlled substances shall include in the inventory, the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section. Each such person who is also registered as a manufacturer or as a distributor shall include in his/her inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).

(5) *Inventories of chemical analysts.* Each person registered or authorized to conduct chemical analysis with controlled substances shall include in his inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section as to substances which have been manufactured, imported, or received by such person. If less than 1 kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I), or less than 20 grams of a hallucinogenic substance listed in Schedule I (other than lysergic acid diethylamide), or less than 0.5 gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory. Laboratories of the Administration may possess up to 150 grams of any hallucinogenic substance in Schedule I without regard to a need for an inventory of those substances. No inventory is required of known or suspected controlled substances received as evidentiary materials for analysis.

#### §§ 1304.12—1304.19 [Removed]

6. Sections 1304.12, 1304.13, 1304.14, 1304.15, 1304.16, 1304.17, 1304.18 and 1304.19 are proposed to be removed.

7. Section 1304.21 is proposed to be amended by revising paragraphs (a) and (c) to read as follows:

#### § 1304.21 General requirements for continuing records.

(a) Every registrant required to keep records pursuant to Section 1304.03 shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, except that no registrant shall be required to maintain a perpetual inventory.

(b) \* \* \*

(c) Separate records shall be maintained by a registrant for each independent activity for which he/she is

registered, except as provided in § 1304.22(d).

\* \* \* \* \*

8. Section 1304.22 is proposed to be revised to read as follows:

#### 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers and exporters.

Each person registered or authorized (by § 1301.13(e) or §§ 1307.11–1307.13 of this chapter) to manufacture, distribute, dispense, import, export or conduct research with controlled substances shall maintain records with the information listed below.

(a) *Records for manufacturers.* Each person registered or authorized to manufacture controlled substances shall maintain records with the following information:

(1) For each controlled substance in bulk form to be used in, or capable of use in, or being used in, the manufacture of the same or other controlled or noncontrolled substances in finished form,

(i) The name of the substance;

(ii) The quantity manufactured in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch manufactured;

(iii) The quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the substance was received;

(iv) The quantity imported directly by the registrant (under a registration as an importer) for use in manufacture by him/her, including the date, quantity, and import permit or declaration number for each importation;

(v) The quantity used to manufacture the same substance in finished form, including:

(A) The date and batch or other identifying number of each manufacture;

(B) The quantity used in the manufacture;

(C) The finished form (e.g., 10-milligram tablets or 10-milligram concentration per fluid ounce or milliliter);

(D) The number of units of finished form manufactured;

(E) The quantity used in quality control;

(F) The quantity lost during manufacturing and the causes therefore, if known;

(G) The total quantity of the substance contained in the finished form;

(H) The theoretical and actual yields; and

(I) Such other information as is necessary to account for all controlled

substances used in the manufacturing process;

(vi) The quantity used to manufacture other controlled and noncontrolled substances, including the name of each substance manufactured and the information required in paragraph (a)(1)(v) of this section;

(vii) The quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address, and registration number of each person to whom a distribution was made;

(viii) The quantity exported directly by the registrant (under a registration as an exporter), including the date, quantity, and export permit or declaration number of each exportation;

(ix) The quantity distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity distributed or disposed;

(x) The originals of all written certifications of available procurement quotas submitted by other persons (as required by § 1303.12(f) of this chapter) relating to each order requiring the distribution of a basic class of controlled substance listed in Schedule I or II.

(2) For each controlled substance in finished form,

(i) The name of the substance;

(ii) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(iii) The number of containers of each such commercial finished form manufactured from bulk form by the registrant, including the information required pursuant to paragraph (a)(1)(v) of this section;

(iv) The number of units of finished forms and/or commercial containers received from other persons, including the date of and number of units and/or commercial containers in each receipt and the name, address, and registration number of the person from whom the units were received;

(v) The number of units of finished forms and/or commercial containers imported directly by the person (under a registration or authorization to import), including the date of, the number of units and/or commercial containers in, and the import permit or declaration number for, each importation.

(vi) The number of units and/or commercial containers manufactured by the registrant from units in finished form received from others or imported, including:

(A) The date and batch or other identifying number of each manufacture;

(B) The operation performed (e.g., repackaging or relabeling);

(C) The number of units of finished form used in the manufacture, the number manufactured and the number lost during manufacture, with the causes for such losses, if known; and

(D) Such other information as is necessary to account for all controlled substances used in the manufacturing process;

(vii) The number of commercial containers distributed to other persons, including the date of and number of containers in each distribution, and the name, address, and registration number of the person to whom the containers were distributed;

(viii) The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation; and

(ix) The number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name address, and registration number of the person to whom distributed, and the quantity in finished form distributed or disposed.

(b) *Records for distributors.* Each person registered or authorized to distribute controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraphs (a)(2) (i), (ii), (iv), (v), (vii), (viii) and (ix) of this section.

(c) *Records for dispensers and researchers.* Each person registered or authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2) (i), (ii), (iv) and (ix) of this section. In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or

administered the substance on behalf of the dispenser.

(d) *Records for importers and exporters.* Each person registered or authorized to import or export controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraphs (a)(2) (i), (iv), (v) and (vii) of this section. In addition, the quantity disposed of in any other manner by the registrant (except quantities used in manufacturing by an importer under a registration as a manufacturer), which quantities are to be recorded pursuant to paragraphs (a)(1) (iv) and (v) of this section; and the quantity (or number of units or volume in finished form) exported, including the date, quantity (or number of units or volume), and the export permit or declaration number for each exportation, but excluding all quantities (and number of units and volumes) manufactured by an exporter under a registration as a manufacturer, which quantities (and numbers of units and volumes) are to be recorded pursuant to paragraphs (a)(1)(xiii) or (a)(2)(xiii) of this section.

**§§ 1304.23—1304.26 [Removed]**

9. Sections 1304.23 through 1304.26 are proposed to be removed.

**§ 1304.27 [Redesignated as § 1304.23]**

10. Section 1304.27 is proposed to be redesignated as § 1304.23.

**§ 1304.28 [Redesignated as § 1304.24 and amended]**

11. Section 1304.28 is proposed to be redesignated as § 1304.24 and reference in § 1304.28(b) to “§ 1304.24” is proposed to be revised to read “§ 1304.22”, and in paragraph (d), the words “part 1401 of this title” are proposed to be revised to read “42 CFR Part 2.”

**§ 1304.29 [Redesignated as § 1304.25]**

12. Section 1304.29 is proposed to be redesignated as § 1304.25.

13. Section 1304.31 is proposed to be revised to read as follows:

**§ 1304.31 Reports from manufacturers importing narcotic raw material.**

(a) Every manufacturer which imports or manufactures from narcotic raw material (opium, poppy straw, and concentrate of poppy straw), shall submit information which accounts for the importation and for all manufacturing operations performed between importation and the production in bulk or finished marketable products, standardized in accordance with the U.S. Pharmacopeia, National Formulary or other recognized medical standards. Reports shall be signed by the

authorized official and submitted quarterly on company letterhead to the Drug Enforcement Administration, Drug and Chemical Evaluation Section, Washington, D.C. 20537, on or before the 15th day of the month immediately following the period for which it is submitted.

(b) The following information shall be submitted for each type of narcotic raw material (quantities are expressed as grams of anhydrous morphine alkaloid):

- (1) Beginning inventory;
- (2) Gains on reweighing;
- (3) Imports;
- (4) Other receipts;
- (5) Quantity put into process;
- (6) Losses on reweighing;
- (7) Other dispositions and
- (8) Ending inventory.

(c) The following information shall be submitted for each narcotic raw material derivative including morphine, codeine, thebaine, oxycodone, hydrocodone, medicinal opium, manufacturing opium, crude alkaloids and other derivatives (quantities are expressed as grams of anhydrous base or anhydrous morphine alkaloid for manufacturing opium and medicinal opium):

- (1) Beginning inventory;
- (2) Gains on reweighing;
- (3) Quantity extracted from narcotic raw material;
- (4) Quantity produced/manufactured/synthesized;
- (5) Quantity sold;
- (6) Quantity returned to conversion processes for reworking;
- (7) Quantity used for conversion;
- (8) Quantity placed in process;
- (9) Other dispositions;
- (10) Losses on reweighing and
- (11) Ending inventory.

(d) The following information shall be submitted for importation of each narcotic raw material:

- (1) Import permit number;
- (2) Date shipment arrived at the United States port of entry;
- (3) Actual quantity shipped;
- (4) Assay (percent) of morphine, codeine and thebaine and
- (5) Quantity shipped, expressed as anhydrous morphine alkaloid.

(e) Upon importation of crude opium, samples will be selected and assays made by the importing manufacturer in the manner and according to the method specified in the U.S. Pharmacopeia. Where final assay data is not determined at the time of rendering report, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.

(f) Where factory procedure is such that partial withdrawals of opium are

made from individual containers, there shall be attached to each container a stock record card on which shall be kept a complete record of all withdrawals therefrom.

(g) All in-process inventories should be expressed in terms of end-products and not precursors. Once precursor material has been changed or placed into process for the manufacture of a specified end-product, it must no longer be accounted for as precursor stocks available for conversion or use, but rather as end-product in-process inventories.

14. Section 1304.32 is proposed to be revised to read as follows:

**§ 1304.32 Reports of manufacturers importing coca leaves.**

(a) Every manufacturer importing or manufacturing from raw coca leaves shall submit information accounting for the importation and for all manufacturing operations performed between the importation and the manufacture of bulk or finished products standardized in accordance with U.S. Pharmacopoeia, National Formulary, or other recognized standards. The reports shall be submitted quarterly on company letterhead to the Drug Enforcement Administration, Drug and Chemical Evaluation Section, Washington, DC 20537, on or before the 15th day of the month immediately following the period for which it is submitted.

(b) The following information shall be submitted for raw coca leaf, ecgonine, ecgonine for conversion or further manufacture, benzoylecgonine, manufacturing coca extracts (list for tinctures and extracts; and others separately), other crude alkaloids and other derivatives (quantities should be reported as grams of actual quantity involved and the cocaine alkaloid content or equivalency):

- (1) Beginning inventory;
- (2) Imports;
- (3) Gains on reweighing;
- (4) Quantity purchased;
- (5) Quantity produced;
- (6) Other receipts;
- (7) Quantity returned to processes for reworking;
- (8) Material used in purification for sale;
- (9) Material used for manufacture or production;
- (10) Losses on reweighing;
- (11) Material used for conversion;
- (12) Other dispositions and
- (13) Ending inventory.

(c) The following information shall be submitted for importation of coca leaves:

- (1) Import permit number;

(2) Date the shipment arrived at the United States port of entry;

(3) Actual quantity shipped;

(4) Assay (percent) of cocaine alkaloid and

(5) Total cocaine alkaloid content.

(d) Upon importation of coca leaves, samples will be selected and assays made by the importing manufacturer in accordance with recognized chemical procedures. These assays shall form the basis of accounting for such coca leaves, which shall be accounted for in terms of their cocaine alkaloid content or equivalency or their total anhydrous coca alkaloid content. Where final assay data is not determined at the time of submission, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.

(e) Where factory procedure is such that partial withdrawals of medicinal coca leaves are made from individual containers, there shall be attached to the container a stock record card on which shall be kept a complete record of withdrawals therefrom.

(f) All in-process inventories should be expressed in terms of end-products and not precursors. Once precursor material has been changed or placed into process for the manufacture of a specified end-product, it must no longer be accounted for as precursor stocks available for conversion or use, but rather as end-product in-process inventories.

**§ 1304.33 [Removed]**

15. Section 1304.33 is proposed to be removed.

**§ 1304.34 [Redesignated as § 1304.33]**

16. Section 1304.34 is proposed to be redesignated as § 1304.33 and revised to read as follows:

**§ 1304.33 Reports to ARCOS.**

(a) *Reports generally.* All reports required by this section shall be filed with the ARCOS Unit, PO/ 28293, Central Station, Washington, DC 20005 on DEA Form 333, or on media which contains the data required by DEA Form 333 and which is acceptable to the ARCOS Unit.

(b) *Frequency of reports.* Acquisition/Distribution transaction reports shall be filed every quarter not later than the 15th day of the month succeeding the quarter for which it is submitted; except that a registrant may be given permission to file more frequently, (but not more frequently than monthly), depending on the number of transactions being reported each time by that registrant. Inventories shall provide

data on the stocks of each reported controlled substance on hand as of the close of business on December 31 of each year. These reports shall be filed not later than January 15 of the following year. Manufacturing transaction reports shall be filed annually for each calendar year not later than January 15 of the following year.

(c) *Persons reporting.* For controlled substances in Schedules I, II or narcotic controlled substances in Schedule III, each person who is registered to manufacture in bulk or dosage form, or package, repack, label or relabel and each person who is registered to distribute shall report acquisition/distribution transactions. In addition to reporting acquisition/distribution transactions, each person who is registered to manufacture controlled substances in bulk or dosage form shall report manufacturing transactions on controlled substances in Schedules I and II, each narcotic controlled substance listed in Schedules III, IV, and V, and on each psychotropic controlled substance listed in Schedules III and IV as identified in paragraph (d) of this section.

(d) *Substances covered.* Manufacturing and acquisition/distribution transaction reports shall include data on each controlled substance listed in Schedules I and II and on each narcotic controlled substance listed in Schedule III (but not on any material, compound, mixture or preparation containing a quantity of a substance having a stimulant effect on the central nervous system, which material, compound, mixture or preparation is listed in Schedule III or on any narcotic controlled substance listed in Schedule V). Additionally, reports on manufacturing transactions shall include the following psychotropic controlled substances listed in Schedules III and IV:

**Schedule III**

- (1) Benzphetamine;
- (2) Cyclobarbitol;
- (3) Methyprylon; and
- (4) Phendimetrazine.

**Schedule IV**

- (1) Barbitol;
- (2) Diethylpropion (Amfepramone);
- (3) Ethchlorvynol;
- (4) Ethinamate;
- (5) Lefetamine (SPA);
- (6) Mazindol;
- (7) Meprobamate;
- (8) Methylphenobarbital;
- (9) Phenobarbital;
- (10) Phentermine; and
- (11) Pipradrol.

Data shall be presented in such a manner as to identify the particular

form, strength, and trade name, if any, of the product containing the controlled substance for which the report is being made. For this purpose, persons filing reports shall utilize the National Drug Code Number assigned to the product under the National Drug Code System of the Food and Drug Administration.

(e) *Transactions reported.*

Acquisition/distribution transaction reports shall provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by Government agencies). Manufacturing reports shall provide data on material manufactured, manufacture from other material, use in manufacturing other material and use in producing dosage forms.

(f) *Exceptions.* A registered institutional practitioner who repackages or relabels exclusively for distribution or who distributes exclusively to (for dispensing by) agents, employees, or affiliated institutional practitioners of the registrant may be exempted from filing reports under this section by applying to the ARCOS Unit of the Administration.

(Approved by the Office of Management and Budget under control number 1117-0003)

**§§ 1304.35—1304.38 [Removed]**

17. Sections 1304.35 through 1304.38 are proposed to be removed.

**PART 1305—[AMENDED]**

1. The authority citation for part 1305 continues to read as follows:

Authority: 21 U.S.C. 821, 828, 871(b) unless otherwise noted.

2. Section 1305.02 is proposed to be revised to read as follows:

**§ 1305.02 Definitions.**

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or Part 1300 of this chapter.

3. Section 1305.03 is proposed to be revised to read as follows:

**§ 1305.03 Distributions requiring order forms.**

An order form (DEA Form 222) is required for each distribution of a Schedule I or II controlled substance except to persons exempted from registration under part 1301 of this chapter; which are exported from the United States in conformity with the Act; or for delivery to a registered

analytical laboratory, or its agent approved by DEA.

4. Section 1305.06 is proposed to be amended to read as follows:

**§ 1305.06 Procedure for executing order forms.**

(a) Order forms shall be prepared and executed by the purchaser simultaneously in triplicate by means of interleaved carbon sheets which are part of the DEA Form 222. Order forms shall be prepared by use of a typewriter, pen, or indelible pencil.

(b) Only one item shall be entered on each numbered line. An item shall consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance. The last line completed shall be noted on that form at the bottom of the form, in the space provided. Order forms for carfentanil, etorphine hydrochloride, and diprenorphine shall contain only these substances.

(c) The name and address of the supplier from whom the controlled substances are being ordered shall be entered on the form. Only one supplier may be listed on any form.

(d) Each order form shall be signed and dated by a person authorized to sign an application for registration. The name of the purchaser, if different from the individual signing the order form, shall also be inserted in the signature space. Unexecuted order forms may be kept and may be executed at a location other than the registered location printed on the form, provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of such location by any officer authorized to make inspections, or to enforce, any Federal, State, or local law regarding controlled substances.

5. Section 1305.07 is proposed to be amended to read as follows:

**§ 1305.07 Power of attorney.**

Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his/her behalf by executing a power of attorney for each such individual. The power of attorney shall be signed by the same person who signed the most recent application for registration or reregistration and by the individual being authorized to obtain and execute order forms. The power of attorney shall be filed with the executed order forms of the purchaser, and shall be retained for the same period as any order form bearing the signature of the attorney. The power of attorney shall be available for inspection together with other order form records. Any power of

attorney may be revoked at any time by executing a notice of revocation, signed by the person who signed (or was authorized to sign) the power of attorney or by a successor, whoever signed the most recent application for registration or reregistration, and filing it with the power of attorney being revoked. The form for the power of attorney and notice of revocation shall be similar to the following:

Power of Attorney for DEA Order Forms

(Name of registrant) \_\_\_\_\_

(Address of registrant) \_\_\_\_\_

(DEA registration number) \_\_\_\_\_

I, \_\_\_\_\_ (name of person granting power), the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint \_\_\_\_\_ (name of attorney-in-fact), \_\_\_\_\_ my true and lawful attorney for me in my name, place, and stead, to execute applications for books of official order forms and to sign such order forms in requisition for Schedule I and II controlled substances, in accordance with section 308 of the Controlled Substances Act (21 U.S.C. 828) and part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney shall lawfully do or cause to be done by virtue hereof.

(Signature of person granting power) \_\_\_\_\_

I, \_\_\_\_\_ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

(Signature of attorney-in-fact) \_\_\_\_\_

Witnesses:

1. \_\_\_\_\_
2. \_\_\_\_\_

Signed and dated on the \_\_\_\_\_ day of \_\_\_\_\_, (year), at \_\_\_\_\_.

Notice of Revocation

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act of the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact \_\_\_\_\_ this same day.

(Signature of person revoking power) \_\_\_\_\_

Witnesses:

1. \_\_\_\_\_
2. \_\_\_\_\_

Signed and dated on the \_\_\_\_\_ day of \_\_\_\_\_, (year), at \_\_\_\_\_.

6. Section 1305.12 is proposed to be amended by revising paragraph (b) to read as follows:

**§ 1305.12 Lost or stolen order forms.**

\* \* \* \* \*  
 (b) Whenever any used or unused order forms are stolen or lost (otherwise than in the course of transmission) by any purchaser or supplier, he/she shall immediately upon discovery of such theft or loss, report the same to the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located, stating the serial number of each form stolen or lost. If the theft or loss includes any original order forms received from purchasers and the supplier is unable to state the serial numbers of such order forms, he/she shall report the date or approximate date of receipt thereof and the names and addresses of the purchasers. If an entire book of order forms is lost or stolen, and the purchaser is unable to state the serial numbers of the order forms contained therein, he/she shall report, in lieu of the numbers of the forms contained in such book, the date or approximate date of issuance thereof. If any unused order form reported stolen or lost is subsequently recovered or found, the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located shall immediately be notified.

7. In addition to the proposed amendments set forth above, DEA is proposing to amend each section indicated in the left column by removing the words indicated in the middle column and adding the words in the right column:

Section	Remove	Add
1305.04(b) ....	his .....	his/her.
1305.05(b) ....	him (twice) ...	him/her.
1305.08(a) ....	he .....	he/she.
1305.08(a) ....	his (twice) ....	his/her.
1305.09(b) ....	he .....	he/she.
1305.09(d) ....	his own .....	his/her own.
1305.10(a) ....	hall .....	shall.
1305.10(a) ....	he .....	he/she.
1305.13(a) ....	He .....	He/She.
1305.13(b) ....	he .....	he/she.
1305.13(c) ....	he .....	he/she.
1305.13(c) ....	1305.06(e) ...	1305.06(d).
1305.14 .....	he (twice) ....	he/she.
1305.14 .....	1301.45 or 1301.46.	1301.36.
1305.16(b) ....	he .....	he/she.

**PART 1306—[AMENDED]**

1. The authority citation for Part 1306 continues to read as follows:

Authority: 21 U.S.C. 821, 829, 871(b).

2. Section 1306.02 is proposed to be revised to read as follows:

**§ 1306.02 Definitions.**

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

3. Section 1306.11 is proposed to be amended by revising paragraphs (a) and (d)(4), and adding a new paragraph (g) to read as follows:

**§ 1306.11 Requirement of prescription.**

(a) A pharmacist may dispense directly a controlled substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the practitioner, except as provided in paragraph (d) of this section. A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in paragraph (e), (f), or (g) of this section. The original prescription shall be maintained in accordance with § 1304.04(h) of this chapter.

\* \* \* \* \*

(d) \* \* \*

(4) Within 7 days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of § 1306.05, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 7 day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Administration if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner.

\* \* \* \* \*

(g) A prescription prepared in accordance with § 1306.05 written for a Schedule II narcotic substance for a

patient released by a registered institution to a home hospice setting which continues to provide daily skilled nursing care to the home hospice setting may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this paragraph (g) and it shall be maintained in accordance with § 1304.04(h) of this chapter.

4. Section 1306.13 is proposed to be amended by revising paragraph (b) to read as follows:

**§ 1306.13 Partial filling of prescriptions.**

\* \* \* \* \*

(b) A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of the Act. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

\* \* \* \* \*

5. Section 1306.14 is proposed to be amended by revising the heading and adding a new paragraph (c) to read as follows:

**§ 1306.14 Labeling of substances and filing of prescriptions.**

\* \* \* \* \*

(c) All written prescriptions and written records of emergency oral prescriptions shall be kept in accordance with requirements of § 1304.04(h) of this chapter.

6. Section 1306.15 is proposed to be removed.

7. The center undesignated heading preceding § 1306.21 and § 1306.21 are proposed to be revised to read as follows:

Controlled Substances Listed in Schedules III, IV, and V

**§ 1306.21 Requirement of prescription.**

(a) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to either a written prescription signed by a practitioner or a facsimile of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy or pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required in § 1306.05, except for the signature of the practitioner.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule III, IV, or V in the course of his/her professional practice without a prescription, subject to § 1306.07.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule III, IV, or V only pursuant to a written prescription signed by an individual practitioner, or pursuant to a facsimile of a written prescription or order for medication transmitted by the practitioner or the practitioner's agent to the institutional practitioner-pharmacist, or pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in § 1306.05 except for the signature of the individual practitioner), or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user, subject to § 1306.07.

8. Section 1306.23 is proposed to be amended by revising the introductory text to read as follows:

**§ 1306.23 Partial filling of prescriptions.**

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible, provided that:

\* \* \* \* \*

9. Section 1306.24 is proposed to be revised to read as follows:

**§ 1306.24 Labeling of substances and filing of prescriptions.**

(a) The pharmacist filling a prescription for a controlled substance listed in Schedule III, IV, or V shall affix to the package a label showing the pharmacy name and address, the serial number and date of initial filling, the name of the patient, the name of the practitioner issuing the prescription, and directions for use and cautionary statements, if any, contained in such prescription as required by law.

(b) The requirements of paragraph (a) of this section do not apply when a controlled substance listed in Schedule III, IV, or V is prescribed for administration to an ultimate user who is institutionalized; provided, that:

(1) Not more than a 34-day supply or 100 dosage units, whichever is less, of the controlled substance listed in Schedule III, IV or V is dispensed at one time;

(2) The controlled substance listed in Schedule III, IV or V is not in the possession of the ultimate user prior to administration;

(3) The institution maintains appropriate safeguards and records the proper administration, control, dispensing, and storage of the controlled substance listed in Schedule III, IV or V; and

(4) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

(c) All prescriptions for controlled substances listed in Schedules III, IV and V shall be kept in accordance with § 1304.04(h) of this chapter.

**§ 1306.25 [Removed]**

10. Section 1306.25 is proposed to be removed.

**§ 1306.26 [Redesignated as § 1306.25 and amended]**

11. Section 1306.26 is proposed to be redesignated as § 1306.25 and amended by revising paragraphs (a) and (b) to read as follows:

**§ 1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.**

(a) The transfer of original prescription information for a controlled substance listed in Schedules III, IV or V for the purpose of refill dispensing is permissible between pharmacies on a one time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization. Transfers are subject to the following requirements:

(1) The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:

(i) Write the word "VOID" on the face of the invalidated prescription.

(ii) Record on the reverse of the invalidated prescription the name, address and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information.

(iii) Record the date of the transfer and the name of the pharmacist transferring the information.

(b) The pharmacist receiving the transferred prescription information shall reduce to writing the following:

(1) Write the word "transfer" on the face of the transferred prescription.

(2) Provide all information required to be on a prescription pursuant to 21 CFR 1306.05 and include:

(i) Date of issuance of original prescription;

(ii) Original number of refills authorized on original prescription;

(iii) Date of original dispensing;

(iv) Number of valid refills remaining and date(s) and locations of previous refill(s);

(v) Pharmacy's name, address, DEA registration number and prescription number from which the prescription information was transferred;

(vi) Name of pharmacist who transferred the prescription.

(vii) Pharmacy's name, address, DEA registration number and prescription number from which the prescription was originally filled;

(3) The original and transferred prescription(s) must be maintained for a period of two years from the date of last refill.

\* \* \* \* \*

**§ Undesignated center heading and § 1306.31 [Removed]**

12. The undesignated heading preceding § 1306.31 and § 1306.31 are proposed to be removed.



**§ 1306.32 [Redesignated as § 1306.26 and amended]**

13. Section 1306.32 is proposed to be redesignated as § 1306.26 and the introductory text and paragraph (a) are revised to read as follows:

**§ 1306.26 Dispensing without prescription.**

A controlled substance listed in Schedules II, III, IV or V which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

(a) Such dispensing is made only by a pharmacist (as defined in Part 1300 of this chapter), and not by a nonpharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery, may be completed by a nonpharmacist);

\* \* \* \* \*

14. In addition to the proposed amendments set forth above, DEA is proposing to amend each section indicated in the left column by removing the words indicated in the middle column and adding the words in the right column:

Section	Remove	Add
1306.03(a)(2)	1301.24(c) ....	1301.22(c).
1306.03(a)(2)	1301.25 .....	1301.23.
1306.05(b) ....	1301.24(c) ....	1301.22(c).
1306.05(c) ....	1301.25 .....	1301.22(c).
1306.22(a)(2)	practioner .....	practitioner.
1306.22(b) ....	retrival .....	retrieval.
1306.22(b)(2)	duing .....	during.
1306.22(b)(4)	Compliance ..	Diversion.

**PART 1307—[AMENDED]**

1. The authority citation for part 1307 continues to read as follows:

Authority: 21 U.S.C. 821, 822(d), 871(b).

2. Section 1307.01 is proposed to be revised to read as follows:

**§ 1307.01 Definitions.**

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or Part 1300 of this chapter.

3. Section 1307.02 is proposed to be revised to read as follows:

**§ 1307.02 Application of State law and other Federal law.**

Nothing in this chapter shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties,

conventions or protocols, or under the law of the State in which he/she desires to do such act nor shall compliance with such parts be construed as compliance with other Federal or State laws unless expressly provided in such other laws.

4. Section 1307.03 is proposed to be revised to read as follows:

**§ 1307.03 Exceptions to regulations.**

Any person may apply for an exception to the application of any provision of this chapter by filing a written request stating the reasons for such exception. Requests shall be filed with the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537. The Administrator may grant an exception in his discretion, but in no case shall he/she be required to grant an exception to any person which is otherwise required by law or the regulations cited in this section.

**§ 1307.12 [Removed]**

5. Section 1307.12 is proposed to be removed.

**§ 1307.13 [Redesignated as § 1307.12]**

6. Section 1307.13 is proposed to be redesignated as § 1307.12.

**§ 1307.14 [Removed]**

7. Section 1307.14 is proposed to be removed.

**§ 1307.15 [Redesignated as § 1307.13]**

8. Section 1307.15 is proposed to be redesignated as § 1307.13.

9. Section 1307.21 is proposed to be amended by revising paragraph (a) to read as follows:

**§ 1307.21 Procedure for disposing of controlled substances.**

(a) Any person in possession of any controlled substance and desiring or required to dispose of such substance may request the Special Agent in Charge of the Administration in the area in which the person is located for authority and instructions to dispose of such substance. The request should be made as follows:

(1) If the person is a registrant, he/she shall list the controlled substance or substances which he/she desires to dispose of on DEA Form 41, and submit three copies of that form to the Special Agent in Charge in his/her area; or

(2) If the person is not a registrant, he/she shall submit to the Special Agent in Charge a letter stating:

(i) The name and address of the person;

(ii) The name and quantity of each controlled substance to be disposed of;

(iii) How the applicant obtained the substance, if known; and

(iv) The name, address, and registration number, if known, of the person who possessed the controlled substances prior to the applicant, if known.

\* \* \* \* \*

10. In addition to the proposed amendments set forth above, DEA is proposing to amend each section indicated in the left column by removing the words indicated in the middle column and adding the words in the right column:

Section	Remove	Add
1307.11(a)(2)	1304.24(e) ...	1304.22(c).
1307.11(a)(2)	1304.24(c) ....	1304.22(c).
1307.11(a)(4)	1301.28 .....	1301.25.
1307.11(b) ....	1301.28 .....	1301.25.
1307.22 .....	28083 .....	20537.

**PART 1308—[AMENDED]**

1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b).

2. Section 1308.02 is proposed to be revised to read as follows:

**§ 1308.02 Definitions.**

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

**§ 1308.04 [Removed]**

3. Section 1308.04 is proposed to be removed.

4. Section 1308.24 is proposed to be amended by removing the Exempt Chemical Preparations Table and revising paragraphs (a) and (i) to read as follows:

**§ 1308.24 Exempt chemical preparations.**

(a) The chemical preparations and mixtures approved pursuant to § 1308.23 are exempt from application of sections 302, 303, 305, 306, 307, 308, 309, 1002, 1003 and 1004 of the Act (21 U.S.C. 822–823, 825–829, 952–954) and § 1301.74 of this chapter, to the extent described in paragraphs (b) to (h) of this section. Substances set forth in paragraph (j) shall be exempt from the application of Sections 305, 306, 307, 308, 309, 1002, 1003 and 1004 of the Act (21 U.S.C. 825–829, 952–954) and §§ 1301.71–1301.73 and 1301.74 (a), (b), (d), (e) and (f) of this chapter to the extent as hereinafter may be provided.

\* \* \* \* \*

(i) A listing of exempt chemical preparations may be obtained by submitting a written request to the Drug and Chemical Evaluation Section, Drug

Enforcement Administration,  
Washington, DC 20537.

\* \* \* \* \*

5. In Section 1308.26(a) the Table of Excluded Veterinary Anabolic Steroid Implant Products is proposed to be removed. As revised, § 1308.26(a) is proposed to read as follows:

**§ 1308.26 Excluded veterinary anabolic steroid implant products.**

(a) The anabolic steroid-containing products, which are expressly intended for administration through implants to cattle or other nonhuman species and which have been approved by the Secretary of Health and Human Services for such administration are excluded from all schedules pursuant to Section 102(41)(B)(I) of the Act (21 U.S.C. 802(41)(B)(I)). A listing of the excluded products may be obtained by submitting a written request to the Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington DC 20537.

\* \* \* \* \*

6. In § 1308.32, the Table of Exempted Prescription Products is proposed to be removed. As revised § 1308.32 is proposed to read as follows:

**§ 1308.32 Exempted prescription products.**

The compounds, mixtures, or preparations which contain a nonnarcotic controlled substance listed in § 1308.12(e) or in § 1308.13 (b) or (c) or in § 1308.14 or in § 1308.15 listed in the Table of Exempted Prescription Products have been exempted by the Administrator from the application of sections 302 through 305, 307 through 309, 1002 through 1004 of the Act (21 U.S.C. 822–825, 827–829, and 952–954) and Sections 1301.13, 1301.22, and §§ 1301.71 through 1301.76 of this chapter for administrative purposes only. An exception to the above is that those products containing butalbital shall not be exempt from the requirement of 21 U.S.C. 952–954 concerning importation, exportation, transshipment and in-transit shipment of controlled substances. Any deviation from the quantitative composition of any of the listed drugs shall require a petition of exemption in order for the product to be exempted. A listing of the Exempted Prescription Products may be obtained by submitting a written request to the Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537.

7. In Section 1308.34, the Table of Exempt Anabolic Steroid Products is proposed to be removed. As revised, § 1308.34 is proposed to read as follows:

**§ 1308.34 Exempt anabolic steroid products.**

The anabolic steroid containing compounds, mixtures, or preparations which have been exempted by the Administrator from application of sections 302 through 309 and 1002 through 1004 of the Act (21 U.S.C. 822–829 and 952–954) and §§ 1301.13, 1301.22, and 1301.71 through 1301.76 of this chapter for administrative purposes only may be obtained by submitting a written request to the Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537.

8. Section 1308.42 is proposed to be revised to read as follows:

**§ 1308.42 Purpose of hearing.**

If requested by any interested person after proceedings are initiated pursuant to § 1308.43 of this chapter, the Administrator shall hold a hearing for the purpose of receiving factual evidence and expert opinion regarding the issues involved in the issuance, amendment or repeal of a rule issuable pursuant to Section 201(a) of the Act (21 U.S.C. 811(a)). Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law. Additional information relating to hearings to include waivers or modification of rules, request for hearing, burden of proof, time and place, and final order are set forth in Part 1316 of this chapter.

**§ 1308.43 [Removed]**

9. Section 1308.43 is proposed to be removed.

**§ 1308.44 [Redesignated as § 1308.43]**

10. Sections 1308.44 is proposed to be redesignated as § 1308.43 and the citation “1308.45” in paragraph (f) is changed to read “1308.44”.

**§ 1308.45 [Redesignated as § 1308.44]**

11. Section 1308.45 is proposed to be redesignated as 1308.44 and the citation “1308.48” in paragraph (e) changed to read “1308.45”.

**§ 1308.46 and 1308.47**

**[Removed]**

12. Sections 1308.46 and 1308.47 are proposed to be removed.

**§§ 1308.48–1308.50 [Redesignate as §§ 1308.45–1308.47]**

13. Sections 1308.48 through 1308.50 are proposed to be redesignated as §§ 1308.45 through 1308.47.

**§ 1308.5 [Removed]**

14. Section 1308.51 is proposed to be removed.

**§ 1308.52 [Redesignated as § 1308.49 and corrected]**

15. Section 1308.52 is proposed to be redesignated as § 1308.49 and the typographical error “withott” in the introductory text is corrected to read “without”.

16. In addition to the proposed amendments set forth above, DEA is proposing to amend each section indicated in the left column by removing the words indicated in the middle column and adding the words in the right column:

Section	Remove	Add
Table of Contents for Part 1308.	1308.52 scheduling.	1308.52 scheduling.
1308.03(a) ....	1301.44 and 1311.43.	1301.35.
1308.12(g) ....	prectrsors .....	precursors.
1308.13(b)(1) .....	quantitive .....	quantitative.
1308.13(b)(1) .....	lirted .....	listed.
1308.13(b)(1) .....	308.32 .....	1308.32.
1308.22 .....	nonnarcotic ....	nonnarcotic.
1308.23(c)(7) .....	1302.01 .....	Part 1300 of this chapter.
1308.23(f) .....	revoje .....	revoke.
1308.24(d) ....	Drug Control	Drug and Chemical Evaluation.
1308.33(a) ....	1308.02 .....	Part 1300 of this chapter.
1308.33(b) ....	1308.02 .....	Part 1300 of this chapter.

**PART 1309—[AMENDED]**

1. The authority citation for part 1309 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 830, 871(b), 875, 877, 958.

2. Section 1309.02 is proposed to be revised to read as follows:

**§ 1309.02 Definitions.**

Any term used in this part shall have the definition set forth in Section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

**§§ 1309.53 and 1309.57 [Removed] and §§ 1309.54–1309.56 [Redesignated as §§ 1309.53–1309.55]**

3. Sections 1309.53 and 1309.57 are proposed to be removed and §§ 1309.54 through 1309.56 are proposed to be redesignated as §§ 1309.53 through 1309.55.

4. In addition to the proposed amendments set forth above, DEA is proposing to remove the words “Section

1310.01(f)(1)(iv) and add in their place the words "Section 1300.01(b)(28)(i)(D)" in the following places:

- (a) Section 1309.02(g)
- (b) Section 1309.21 (a) and (b)
- (c) Section 1309.25 (a) and (b); and
- (d) Section 1309.71(a)(2).

#### PART 1310—[AMENDED]

1. The authority citation for part 1310 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 871(b).

2. Section 1310.01 is proposed to be revised to read as follows:

#### § 1310.01 Definitions.

Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

#### § 1310.05 [Amended]

2. Section 1310.05(c) is proposed to be amended removing the words "as defined in § 1310.01(i)" and "as defined in § 1310.01(j)"

#### § 1310.08 [Amended]

3. Section 1310.08, introductory text, is proposed to be amended removing the

words "contained in 21 CFR 1310.01(f) and 1313.02(d)"

#### § 1310.09 [Removed]

4. Section 1310.09 is proposed to be removed.

5. In addition to the proposed amendments set forth above, DEA is proposing to amend each section indicated in the left column by removing the words indicated in the middle column and adding the words in the right column:

Section	Remove	Add
1310.10(a) .....	1310.01(f)(1)(iv)	1300.01(b)(28)(i)(D).
1310.14(a) .....	1310.01(f)(1)(iv)(A)	1300.01(b)(28)(i)(D)(1).
1310.15(d) .....	1310.01(f)(1)(iv)(A)	1300.01(b)(28)(i)(D)(1).

#### PART 1311—[REMOVED AND RESERVED]

Part 1311 is proposed to be removed and reserved.

#### PART 1312—[AMENDED]

1. The authority citation for part 1312 continues to read as follows:

Authority: 21 U.S.C. 952, 953, 954, 957, 958.

2. Section 1312.02 is proposed to be revised to read as follows:

#### § 1312.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or Part 1300 of this chapter.

3. Part 1312 is proposed to be amended to remove the words, "1405 EYE Street, NW.", in the following sections:

- (a) 1312.12(a);
- (b) 1312.16(b);
- (c) 1312.18(b);
- (d) 1312.19(b);
- (e) 1312.22(a);

- (f) 1312.24(a);
- (g) 1312.27(a);
- (h) 1312.27(b)(5)(iv);
- (i) 1312.28(d);
- (j) 1312.31(b); and
- (k) 1312.32(a).

4. In addition to the proposed amendments set forth above, DEA is proposing to amend each section indicated in the left column by removing the words indicated in the middle column and adding the words in the right column:

Section	Remove	Add
1312.12(a) .....	Drug Control Section .....	Drug Operations Section.
1312.14(a) .....	Drug Control Section .....	Drug Operations Section.
1312.16(b) .....	Drug Control Section .....	Drug Operations Section.
1312.17 .....	304 .....	1304.
1312.18(b) .....	Drug Control Section .....	Drug Operations Section.
1312.18(c) .....	(or BND) .....	
1312.19(a) .....	Drug Control Section .....	Drug Operations Section.
1312.19(b) .....	Drug Control Section .....	Drug Operations Section.
1312.22(a) .....	Drug Control Section .....	Drug Operations Section.
1312.24(a) .....	Bureau .....	Administration.
1312.24(a) .....	Drug Control Section .....	Drug Operations Section.
1312.25 .....	Drug Control Section .....	Drug Operations Section.
1312.27(a) .....	registered .....	registered.
1312.27(a) .....	Drug Control Section .....	Drug Operations Section.
1312.27(b)(5)(iii) .....	initial .....	initial.
1312.27(b)(5)(iv) .....	Drug Control Section .....	Drug Operations Section.
1312.28(d) .....	Drug Control Section .....	Drug Operations Section.
1312.28(d) .....	1327.27(b)(4) .....	1312.27(b)(4).
1312.31(b) .....	Drug Control Section .....	Drug Operations Section.
1312.32(a) .....	Drug Control Section .....	Drug Operations Section.

#### PART 1313—[AMENDED]

1. The authority citation for part 1313 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 871(b), 971.

2. Section 1313.02 is proposed to be revised to read as follows:

#### § 1313.02 Definitions.

Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

3. Section 1313.15(a) is proposed to be amended by removing the words "§ 1313.02(i)" and replace them with the words "§ 1300.01(b)(13)"

4. Section 1313.21(c)(1) is proposed to be amended by removing the words "as defined § 1313.02(j)"

5. Section 1313.24(a) is proposed to be amended by removing the words "§ 1313.02(j)" and replacing them with the words "§ 1300.01(b)(12)"

**PART 1316—[AMENDED]**

1. The authority citation for part 1316 continues to read as follows:

Authority: 21 U.S.C. 822(f), 871(b), 880, 958(f), 965.

2. Section 1316.02 is proposed to be amended by revising paragraph (g) to read as follows:

**§ 1316.02 Definitions.**

\* \* \* \* \*

(g) Any term not defined in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

3. Section 1316.13 is proposed to be amended by revising the text to read as follows:

**§ 1316.13 Frequency of administrative inspections.**

Except where circumstances otherwise dictate, it is the intent of the Administration to inspect all manufacturers of controlled substances listed in Schedules I and II and distributors of controlled substances listed in Schedule I once each year. Distributors of controlled substances listed in schedules II through V and manufacturers of controlled substances listed in Schedules III through V shall be inspected as circumstances may require, based in part on the registrant's history of compliance with the requirements of this chapter and maintenance of effective controls and procedures to guard against the diversion of controlled substances.

4. Section 1316.42 is proposed to be amended by revising paragraph (h) to read as follows:

**§ 1316.42 Definitions.**

\* \* \* \* \*

(h) Any term not defined in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

5. Section 1316.71 is proposed to be amended by revising paragraph (f) to read as follows:

**§ 1316.71 Definitions.**

\* \* \* \* \*

(f) Any term not defined in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

6. In addition to the proposed amendments set forth above, DEA is proposing to amend each section indicated in the left column by removing the words indicated in the middle column and adding the words in the right column:

Section	Remove	Add
1316.03, introductory text	Adminirtrator	Administrator.
1316.05	1314.06	1316.06.
1316.05	1316.09–1316.14	1316.09–1316.13.
1316.23(b)	1405 I Street	
1316.24(c)	1316.21(b)	1316.23(b).
1316.24(c)	1316.22(b)	1316.24(b).
1316.41	1303.41–1303.47	1303.31–1303.37.
1316.46(b)(1)		1313.51–1313.57.
1316.52(a)	1301.32(a)(3)	1301.32(a)(6).
1316.77(a)	1301.60	1301.56.
1316.81	Forward proceeding	Forward proceeding.

Dated: February 26, 1996.

Stephen H. Greene,

*Deputy Administrator, Drug Enforcement Administration.*

[FR Doc. 96-4663 Filed 3-4-96; 8:45 am]

BILLING CODE 4410-09-P

**DEPARTMENT OF THE INTERIOR****Office of Surface Mining Reclamation and Enforcement****30 CFR Part 906**

[SPATS No. CO-029-FOR]

**Colorado Regulatory Program**

**AGENCY:** Office of Surface Mining Reclamation and Enforcement, Interior.

**ACTION:** Proposed rule; reopening and extension of public comment period on proposed amendment.

**SUMMARY:** The Office of Surface Mining Reclamation and Enforcement (OSM) is announcing receipt of revisions pertaining to a previously proposed

amendment to the Colorado regulatory program (hereinafter, the "Colorado program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The revisions of Colorado's proposed rules pertain to the definitions of "Permit area" and "Self-bonding;" permit application information concerning the legal right to enter and proposed operations in which the affected area is within 100 feet of a public road; the content of public notices in which the affected areas would be within 100 feet of a public road or operations which propose to close or relocate a public road; decisions on requests to disclose confidential information; the area of the proposed surface coal mining operation which is subject to the requirements concerning valid existing rights; the right to comment on technical revisions; approval of and conditions for self bonds; the requirements for vegetative cover at the time of release of bond coverage for liability associated with temporary drainage and sediment

control facilities; and the contents of a showing in lieu of the requirement for an engineer's certification of the construction or reconstruction of haul and access roads that were completed prior to August 1, 1995. The amendment is intended to revise the Colorado program to be consistent with the corresponding Federal regulations, incorporate the additional flexibility afforded by the revised Federal regulations, and improve operational efficiency.

**DATES:** Written comments must be received by 4:00 p.m., m.s.t. March 20, 1996.

**ADDRESSES:** Written comments should be mailed or hand delivered to James F. Fulton at the address listed below. Copies of the Colorado program, the proposed amendment, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free

copy of the proposed amendment by contacting OSM's Denver Field Division.

James F. Fulton, Chief, Denver Field Division, Western Regional Coordinating Center, Office of Surface Mining Reclamation and Enforcement, 1999 Broadway, Suite 3300, Denver, Colorado 80202  
Colorado Division of Minerals and Geology, Department of Natural Resources, 215 Centennial Building, 1313 Sherman Street, Denver, Colorado 80203, Telephone: (303) 866-3567

**FOR FURTHER INFORMATION CONTACT:**  
James F. Fulton, Telephone: (303) 672-5524.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background on the Colorado Program**

On December 15, 1980, the Secretary of the Interior conditionally approved the Colorado program. General background information on the Colorado program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Colorado program can be found in the December 15, 1980, Federal Register (45 FR 82173). Subsequent actions concerning Colorado's program and program amendments can be found at 30 CFR 906.15, 906.16, and 906.30.

##### **II. Proposed Amendment**

By letter dated November 20, 1995, Colorado submitted a proposed amendment to its program (administrative record No. CO-675) pursuant to SMCRA (30 U.S.C. 1201 *et seq.*). Colorado submitted the proposed amendment at its own initiative; in partial response to May 7, 1986, and March 22, 1990, letters (administrative record No. CO-282 and CO-496) that OSM sent to Colorado in accordance with 30 CFR 732.17(c); and in response to the requirement that Colorado amend its program at 30 CFR 906.16(a).

OSM announced receipt of the proposed amendment in the December 7, 1995, Federal Register (60 FR 62789), provided an opportunity for a public hearing or meeting on its substantive adequacy, and invited public comment on its adequacy (administrative record No. CO-675-2). Because no one requested a public hearing or meeting, none was held. The public comment period ended on January 8, 1996.

During its review of the amendment, OSM identified a concern relating to Rule 3.02.4(1)(c), concerning the regulatory authority's discretionary acceptance of self bonds, in addition to apparent typographical errors. OSM

notified Colorado of the concern and typographical errors by letter dated January 25, 1996 (administrative record No. CO-675-8). Colorado responded in a letter dated February 16, 1996, by submitting a revised amendment (administrative record No. CO-675-9).

Colorado proposes revisions to: Rule 1.04(89), concerning the definition of "Permit area," to provide gender-neutral language;

Rule 1.04(116), concerning the definition of "Self-bonding," to replace the words "regulatory authority" with the word "Division;"

Rule 2.03.6(1), concerning right of entry information, to clarify that a permit application must include a legal description of the permit boundary for which the applicant has the legal right of entry;

Rule 2.07.3(2)(e), concerning permit applications for operations in which proposed affected areas would be within 100 feet of a public road, to clarify that the 100 feet is to be measured horizontally;

Rules 2.07.3(2) (e) and (f), concerning the content of a public notice for an operation in which the proposed affected area would be within 100 feet, measured horizontally, of a public road, or an operation which proposes to close or relocate a public road, to clarify that the public notice must include information regarding the availability of a public hearing;

Rule 2.07.5(2)(c), concerning confidential information for which persons have sought disclosure, to clarify that the information will be released only after Colorado has made a decision allowing such disclosure;

Rule 2.07.6(2)(d), concerning valid existing rights, to clarify that it is the affected area of the proposed surface coal mining and reclamation operation which is subject to the requirements concerning valid existing rights;

Rule 2.08.4(6)(b)(ii), concerning proposed technical revisions, to clarify that interested parties have the right to comment on the proposed revision;

Rule 3.02.4(1)(c), concerning approval of a self bond, to clarify that the decision by Colorado to accept a self bond is discretionary;

Rule 3.02.4(2)(e)(v)(B), concerning the conditions for a self bond, to clarify which corporate officers must sign an indemnity agreement;

Rule 3.03.1(5), concerning the release of bond coverage for liability associated with temporary drainage and sediment control facilities, to clarify that, at bond release, the vegetative cover must be adequate to control erosion and similar to the reclaimed area or surrounding undisturbed area; and

Rules 4.03.1(1)(d)(ii) and 4.03.2(1)(f)(ii), concerning an exemption from the requirement for an engineer's certification of the construction or reconstruction of haul and access roads that were completed prior to August 1, 1995, if the applicant provides a showing that the road meets the performance standards of Rule 4.03.2, to clarify that Colorado has the right to determine what information must be included in a relevant showing.

##### **III. Public Comment Procedures**

OSM is reopening the comment period on the proposed Colorado program amendment to provide the public an opportunity to reconsider the adequacy of the proposed amendment in light of the additional materials submitted. In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed revisions to the amendment satisfy the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Colorado program.

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under "DATES" or at locations other than the Denver Field Office will not necessarily be considered in the final rulemaking or included in the administrative record.

##### **IV. Procedural Determinations**

###### **1. Executive Order 12866**

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

###### **2. Executive Order 12778**

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (Civil Justice Reform) and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the

submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

### 3. National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

### 4. Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

### 5. Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal that is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

#### List of Subjects in 30 CFR Part 906

Intergovernmental relations, Surface mining, Underground mining.

Dated: February 27, 1996

Russell F. Price,

Acting Regional Director, Western Regional Coordinating Center.

[FR Doc. 96-5109 Filed 3-4-96; 8:45 am]

BILLING CODE 4310-05-M

## 30 CFR Part 936

[SPATS No. OK-017-FOR]

### Oklahoma Regulatory Program

**AGENCY:** Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

**ACTION:** Proposed rule; public comment period and opportunity for public hearing.

**SUMMARY:** OSM is announcing receipt of a proposed amendment to the Oklahoma regulatory program (hereinafter referred to as the "Oklahoma program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment consists of a revision to the Oklahoma regulations that adds a new permit condition concerning protected activity. The proposed amendment is intended to revise the Oklahoma regulations to be consistent with the Federal regulations.

**DATES:** Written comments must be received by 4:00 p.m., c.s.t. April 4, 1996. If requested, a public hearing on the proposed amendment will be held on April 1, 1996. Requests to speak at the hearing must be received by 4:00 p.m., c.s.t. on March 20, 1996.

**ADDRESSES:** Written comments and requests to speak at the hearing should be mailed or hand delivered to Jack R. Carson, Acting Director, Tulsa Field Office at the first address listed below.

Copies of the Oklahoma program, the proposed amendment, a listing of any scheduled public hearings, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Tulsa Field Office.

Jack R. Carson, Acting Director, Tulsa Field Office, Office of Surface Mining Reclamation and Enforcement, 5100 East Skelly Drive, Suite 470, Tulsa, Oklahoma 74135-6547, Telephone: (918) 581-6430

Oklahoma Department of Mines, 4040 N. Lincoln, Suite 107, Oklahoma City, Oklahoma 73105, Telephone: (405) 521-3859

**FOR FURTHER INFORMATION CONTACT:** Jack R. Carson, Acting Director, Tulsa Field Office, Telephone: (918) 581-6430.

#### SUPPLEMENTARY INFORMATION:

##### I. Background on the Oklahoma Program

On January 19, 1981, the Secretary of the Interior conditionally approved the Oklahoma program. Background information on the Oklahoma program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the January 19, 1981, Federal Register (46 FR 4902). Subsequent actions concerning Oklahoma's program and

program amendments can be found at 30 CFR 936.10, 936.15, and 936.16.

## II. Discussion of the Proposed Amendment

By letter dated February 21, 1996, Oklahoma submitted a proposed amendment to its program pursuant to SMCRA (Administrative Record No. OK-973). Oklahoma submitted the proposed amendment at its own initiative. The provisions of the Oklahoma regulations that Oklahoma proposes to amend are at Oklahoma Administrative Code (OAC) 460:20-15-7 concerning permit conditions. Specifically, Oklahoma proposes to revise OAC 460:20-15-7 by adding a new permit condition at subsection (5) concerning protected activity that reads as follows.

(5) No person shall discharge or in any other way discriminate against or cause to be fired or discriminated against any employee or any authorized representative of employees because that employee or representative has—

(A) Filed, instituted or caused to be filed or instituted any proceedings under the Act by—

(1) Reporting alleged violations or dangers to the Secretary, the State Regulatory Authority, or the employer or his representative;

(2) Requesting an inspection or investigation; or

(3) Taking any other action which may result in a proceeding under the Act.

(B) Made statements, testified, or is about to do so—

(1) In any informal or formal adjudicatory proceeding;

(2) In any informal conference proceeding;

(3) In any rulemaking proceeding;

(4) In any investigation, inspection or other proceeding under the Act;

(5) In any judicial proceeding under the Act.

(C) Has exercised on his own behalf or on behalf of others any right granted by the Act.

(D) Each employer conducting operations which are regulated under this Act, shall within 30 days from the effective day of these regulations, provide a copy of this part to all current employees and to all new employees at the time of their hiring.

Existing subsections (5) through (8) are renumbered (6) through (9).

## III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR

732.15. If the amendment is deemed adequate, it will become part of the Oklahoma program.

#### *Written Comments*

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Tulsa Field Office will not necessarily be considered in the final rulemaking or included in the Administrative Record.

#### *Public Hearing*

Persons wishing to speak at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., c.s.t. on March 20, 1996. The location and time of the hearing will be arranged with those persons requesting the hearing. If no one requests an opportunity to testify at the public hearing, the hearing will not be held. Any disabled individual who has need for a special accommodation to attend a public hearing should contact the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to speak have been heard. Persons in the audience who have not been scheduled to speak, and who wish to do so, will be heard following those who have been scheduled. The hearing will end after all persons scheduled to speak and persons present in the audience who wish to speak have been heard.

#### *Public Meeting*

If only one person requests an opportunity to speak at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendment may request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings will be open to the public and, if possible, notices of meetings will be posted at the locations listed under **ADDRESSES**. A written summary of each meeting will be made a part of the Administrative Record.

## IV. Procedural Determinations

### *Executive Order 12866*

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

### *Executive Order 12778*

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

### *National Environmental Policy Act*

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

### *Paperwork Reduction Act*

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

### *Regulatory Flexibility Act*

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon corresponding Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that

existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the corresponding Federal regulations.

### List of Subjects in 30 CFR Part 936

Intergovernmental relations, Surface mining, Underground mining.

Dated: February 28, 1996.

Brent Wahlquist,

*Regional Director, Mid-Continent Regional Coordinating Center.*

[FR Doc. 96-5107 Filed 3-4-96; 8:45 am]

BILLING CODE 4310-05-M

## Bureau of Land Management

### 43 CFR Chapter II

[WO-310-3110-02 1A]

### Promotion of Development, Reduction of Royalty for Marginal Gas Properties

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of request for information and suggestions regarding an incentive for producers of marginal gas from Federal leases.

**SUMMARY:** The Bureau of Land Management (BLM) is seeking public comments and suggestions on a possible incentive for producers of marginal gas from Federal leases. The incentive would encourage continued production through a possible reduction in Federal royalties for producers of marginally economic gas properties. If the comments indicate that such a reduction in royalties is warranted and will result in a greater ultimate recovery of gas resources (without a net loss in revenues to the states and/or the Federal government), the BLM will initiate a public outreach program in order to discuss comments and suggestions received as a result of this request. Based upon those meetings, the BLM will prepare a proposed rule for subsequent publication.

**DATES:** Written comments should be received on or before June 3, 1996.

**ADDRESSES:** Dr. John W. Bebout, Senior Technical Specialist, Bureau of Land Management (WO-301), 1849 C Street, NW, Washington, D.C. 20240.

**FOR FURTHER INFORMATION CONTACT:** Dr. John W. Bebout (BLM) (202) 452-0340.

**SUPPLEMENTARY INFORMATION:** The United States has a vast and diverse natural gas resource base. In their 1992 study entitled *The Potential for Natural*

Gas in the United States, the National Petroleum Council (NPC) concluded that the technically recoverable natural gas resource base is 1,295 trillion cubic feet (TCF) for the lower 48 states. Of this amount, 600 TCF was believed to be recoverable in the future at a wellhead price of \$2.50 per million British thermal unit (1990 dollars). According to the NPC (Marginal Wells, July 1994), however, the wellhead price on a current basis trended upward to a high of \$2.66 per thousand cubic feet (MCF) during the 1974–1984 period and has declined to around \$1.60–\$1.80 per MCF over the last eight years.

There is a legitimate concern that low gas prices will result in premature abandonment of the marginal properties with the concurrent loss of potentially recoverable reserves as well as royalties, taxes and employment opportunities. A 1992 study by the Interstate Oil and Gas Compact Commission estimated that there were approximately 215,000 idle or shut-in oil, gas and injection wells in the United States at that time. The NPC believes that as many as 50 percent of these wells are gas and injection wells. While some of these wells are undoubtedly shut-in or temporarily abandoned while waiting for pipeline connections, a large portion of these gas wells are idle because they are uneconomical to produce as a result of low producing rates, low gas prices and/or high operating costs (NPC, Marginal Wells, July 1994).

It is clear that whatever combination of price and cost factors currently define the economic limit of a marginal gas well, production-based incentives will improve gas well economics and extend their lives. Because premature abandonment of marginal wells results in the loss of domestic reserves, such incentives may be the only way to maintain the economic viability of the production and resources that these wells represent.

Comments and suggestions on a reduction in Federal royalties should concentrate not only on the value of a royalty rate reduction for producers of marginal gas, but also on how the royalty rate reduction might best be implemented. Respondents should particularly consider the following issues:

1. The need for economic relief for marginal gas properties. Respondents, both for and against the proposal, should document any economic arguments to the extent practicable. The documentation should include all economic assumptions used for estimated costs, profits, effects on employment, etc. The BLM would

especially appreciate detailed source citations for verification and reference.

2. A workable definition of a “marginal” gas property. Before its repeal, the Natural Gas Policy Act of 1978 defined a “stripper” gas well as one producing 60,000 cubic feet of gas or less per day (MCF/D). For Minerals Management Service accounting purposes, however, any proposal for royalty reductions should be based on a property (i.e., units, communitization agreements, leases, etc.) rather than a well-by-well basis.

3. Discouraging false reporting and manipulation. Proposals should describe measures to discourage manipulation of production rates in order to qualify for a royalty reduction. In addition, it would be useful to the BLM if respondents would suggest possible requirements for qualification and the time frames for subsequent qualification periods, if applicable.

4. Minimal administrative burden. All proposals should be designed in a manner which minimizes the administrative burden placed upon the government and private industry. For example, consideration might be given to a notification process rather than a formal application process.

5. Minimal Program Overlap. When preparing proposals, special consideration should be given to avoiding overlap with existing programs such as the Heavy Oil and Stripper Property royalty rate reductions.

Dated: February 26, 1996.

Sylvia V. Baca,

*Deputy Assistant Secretary of the Interior.*

[FR Doc. 96–4975 Filed 3–4–96; 8:45 am]

BILLING CODE 4310–84–P

## Minerals Management Service

### 43 CFR Part 14

#### Aboriginal Title To The Alaska Outer Continental Shelf

**AGENCY:** Minerals Management Service (MMS), Department of the Interior.

**ACTION:** Notice of receipt of petition for rulemaking and request for comments.

**SUMMARY:** The Department of the Interior announces receipt of, and requests comments on, a petition for rulemaking on issues regarding claimed aboriginal title and aboriginal hunting and fishing rights of federally recognized tribes in Alaska exercisable on the federal Outer Continental Shelf (OCS).

**DATES:** Comments on the petition are requested through April 4, 1996.

**ADDRESSES:** Comments on the petition should be directed to: Paul Stang, Chief, Branch of Leasing Coordination, Office of Program Development and Coordination, (MS–4410) Minerals Management Service, 381 Elden Street, Herndon, Virginia 20270–4817. Please indicate that your comment is in response to the petition for rulemaking on aboriginal title and rights on the Alaska OCS.

**FOR FURTHER INFORMATION CONTACT:**

William Quinn at (703) 787–1191.

**SUPPLEMENTARY INFORMATION:** The Villages of Eyak, Tatilek, Chenega, Port Graham and Nanwalek have petitioned the Secretary to promulgate a rule stating that 225 federally recognized tribes in Alaska may claim aboriginal title and aboriginal hunting and fishing rights to the Outer Continental Shelf (OCS) and to make leases on the OCS off Alaska subject to claimed aboriginal title and rights of such tribes. The MMS is the agency within the Department of the Interior responsible for issuing and managing mineral leases on the OCS pursuant to the Outer Continental Shelf Lands Act, 43 U.S.C. 1331 *et seq.*, hence its involvement in this matter.

The initial petition was addressed to both the Secretary of the Interior and the Secretary of Commerce and did not designate any existing rule for revision or propose a new rule text. Therefore, the Secretary's office notified the Villages that under 43 CFR 14.2, a petition for rulemaking must include the text of a rule that the petitioner proposes for adoption. On September 1, 1995, the Solicitor of the Department received a letter from counsel for the petitioning Villages proposing the following rule:

“Proposed regulation of the Secretary of the Interior for the protection of aboriginal title and aboriginal hunting and fishing rights on the Outer Continental Shelf of federally recognized tribes in Alaska.

“1. The Department recognizes that the 225 native Villages on the Secretary's list of “Native Entities within the State of Alaska Recognized and Eligible to Receive Services from the United States Bureau of Indian Affairs,” 60 Fed. Reg. 9250, February 16, 1995, are Native Tribes capable of possessing aboriginal claims. *County of Oneida v. Oneida Indian Nation*, 470 U.S. 226, 233 (1974).

“2. Although the existence and scope of the aboriginal titles of individual Alaskan tribes has not yet been determined, based on the historical and contemporary evidence available the Department recognizes that many Alaska coastal tribes have continuously and exclusively occupied areas of the OCS off Alaska for long periods of time and thus possess the potential to establish prima facie



cases of aboriginal title to their respective traditional use areas.

"3. The Department recognizes that the aboriginal title and rights of such tribes were not extinguished by the Alaska Native Claims Settlement Act (ANCSA), 43 U.S.C. 1601, et seq., the Outer continental Shelf Lands Act, 43 U.S.C. 1331, et seq. or by any other Congressional Act. Nor, is the continuing existence of such rights contrary to the Paramountcy Doctrine (see *United States v. California*, 332 U.S. 19 (1947); *United States v. Maine*, 420 U.S. 515 (1975); and *United States v. Louisiana*, 339 U.S. 699 (1950) or to the Ninth Circuit decisions in *Native Village of Gambell v. Hodel*, 869 F.2d 1273 (9th Cir. 1989) (*Gambell III*) or *Gambell v. Babbitt*, 999 F.2d 403 (9th Cir. 1993) (*Gambell IV*).

"4. Hereafter all Alaska native tribes whose aboriginal territory or aboriginal rights to the OCS would likely suffer trespass or be disturbed or affected in any significant way by Departmental leases of the OCS off the coast of Alaska, shall be given written notice of such sale and of this regulation at least 180 days prior to the official sale of such leases. Oil, gas, or other mineral leases that would likely cause disruptive effects merely by nature of their proximity to aboriginal territory are included within this notice requirement.

"The types of disruptions or effects requiring such prior notice include any potential trespass upon the tribes' aboriginal hunting and fishing grounds, or any potentially significant disturbance, depletion, or interference with Native hunting, fishing or exploitation of other resources or other uses of their aboriginal territory.

"5. The Department recognizes that all existing as well as future leases of the OCS off Alaska are subject to the aboriginal title and aboriginal hunting and fishing rights of Alaskan Native Tribes."

The matter addressed in the petition has been the subject of litigation for many years now and is currently the subject of litigation brought by the petitioning Villages seeking to halt proposed OCS Lease Sale 149 in the Cook Inlet in Alaska. *Native Village of Eyak, et al. v. Trawler Diane Marie, Inc., et al.*, Case No. A95-0063 CIV (HRH) (D. Alaska, filed Feb. 23, 1995). The Government has consistently taken the position that no person or entity has title to, or hunting and fishing rights on, the Alaska OCS. Rather, the Alaska OCS is subject to the paramount authority of the Federal Government, and to uses permitted by the United States pursuant to the Outer Continental Shelf Lands Act, 43 U.S.C. 1331 et seq.

Nevertheless, in fairness to the Villages, the MMS is publishing the text of the rule pursuant to 43 CFR part 14 and invites knowledgeable parties to comment on it and to consider the following:

1. Should we engage in this rulemaking?
2. Would such a rule be consistent with the laws governing the OCS?

3. Would granting the rule be consistent with the paramount interest of the United States?

4. Do we have other mechanisms sufficient to protect claimed Native interests? and,

5. Where should undertaking such rulemaking fit in among the other priorities of the agency?

Anyone so wishing should submit comments to MMS at the address above. In a separate Federal Register notice, MMS is also pursuing factual inquiry into the potential nature and extent of the claims of the five petitioning Villages with respect to the areas proposed for lease in Cook Inlet Sale 149 and Gulf of Alaska-Yakutat Sale 158 in connection with the decisions to conduct such sales.

Dated: February 26, 1996.  
Cynthia Quarterman,  
Director, Minerals Management Service.  
[FR Doc. 96-5009 Filed 3-4-96; 8:45 am]  
BILLING CODE 4310-MR-M

## DEPARTMENT OF TRANSPORTATION

### Coast Guard

#### 46 CFR Parts 108, 110, 111, 112, 113, and 161

[CGD 94-108]

RIN 2115-AF24

#### Electrical Engineering Requirements for Merchant Vessels

AGENCY: Coast Guard, DOT.

ACTION: Correction to proposed rule.

**SUMMARY:** This document contains corrections to the notice of proposed rulemaking, which was published Friday, February 2, 1996, as part of the President's Regulatory Reinvention Initiative, the proposed rule amends the Coast Guard's electrical engineering regulations.

**EFFECTIVE DATE:** March 5, 1996.

**FOR FURTHER INFORMATION CONTACT:** Mr. Gerald P. Miente, Project Manager, or LT(jg) Jacqueline M. Twomey, Project Engineer, Design and Engineering Standards Division (G-MMS), (202) 267-2206.

#### SUPPLEMENTARY INFORMATION:

##### Background

The notice of proposed rulemaking that is the subject of these corrections amends the Coast Guard's electrical engineering regulations to reduce the regulatory burden on the marine industry, purge obsolete regulations and replaces prescriptive requirements with

performance-based regulations that incorporate international standards.

#### Need for Correction

As published, the final rule contains typographical errors and omissions which may prove to be misleading and are in need of correction.

#### Correction of Publication

Accordingly, the publication on February 2, 1996, of the notice of proposed rulemaking at 61 FR 4132, which was the subject of FR Doc. 96-2149, is corrected as follows:

1. On page 4135, in the first column, in the paragraph entitled "Section 111.05-33," sixth line, the word "a" should be added before the word "current."

2. On the same page, in the second column, in the paragraph entitled "Section 111.12-1," seventh line, remove the word "governor" and add, in its place, the words "overspeed device".

3. On page 4136, in the first column, in the paragraph entitled "Section 111.30-4," tenth line, remove the words "a section", and add in their place the word "sections".

4. On page 4137, in the first column, in the paragraph entitled "Section 111.60-3," fourth line, "IEC Publication 352" should be replaced with "IEC Publication 92-352".

5. On page 4146, in the list of Underwriters Laboratories' standards, the section affected for UL 62, Flexible Cord and Fixture Wire, should read "111.60-13(a)".

6. On page 4153, in the second column, in § 111.60-13(a), fourth and fifth lines, remove the words "NEMA WC 3 and NEMA WC 8" and add, in their place the words, "NEMA WC 3, NEMA WC 8 or UL 62."

7. On page 4159, in the third column, in the paragraph numbered "154," second line, remove "(q)" and add, in its place, "(g)".

8. On page 4161, in the third column, in the paragraph numbered "184," second and third lines, remove the words "(g), (h), and (i) are revised and paragraph (j) is added" and add, in their place, the words "(g) and (h) and paragraphs (i) and (j) are added".

9. On page 4163, in the first column, in § 113.50-5(g), fourth line, add the word "or" before "4X".

10. On the same page, in the second column, in the paragraph numbered "201," third line, add the words "paragraph (e) is removed;" before the words "and Table 1135.50-15" and after § 113.50-15(d) remove the five asterisks.

Dated: February 26, 1996.

Joseph J. Angelo,

*Director for Standards, Office of Marine Safety, Security and Environmental Protection.*

[FR Doc. 96-5060 Filed 3-4-96; 8:45 am]

BILLING CODE 4910-14-M

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 651

[Docket No. 960216032-6032-01; I.D. 021296E]

RIN 0648-AH70

#### Northeast Multispecies Fishery; Amendment 7

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Proposed rule; request for comments.

**SUMMARY:** NMFS proposes regulations to implement Amendment 7 to the Northeast Multispecies Fishery Management Plan (FMP). These regulations would: Establish an annual target Total Allowable Catch (TAC) for regulated species; accelerate the current days-at-sea (DAS) effort reduction program; eliminate most of the current exemptions to the effort control program; add new closed areas; restrict fisheries in the Gulf of Maine/Georges Bank (GOM/GB) and Southern New England (SNE) regulated mesh areas having more than a minimal bycatch of regulated species; establish a possession limit for vessels 30 ft (9.1 m) or less in length; establish the current experimental Nantucket Shoals dogfish fishery as an exempted fishery; modify the permit categories; establish restrictions on charter or party, and recreational vessels; revise and expand the existing framework provisions; and revise the harbor porpoise protection framework procedures. The intended effect of this rule is to rebuild multispecies stocks.

**DATES:** Comments are invited on the proposed Amendment 7 and its supporting documents, including the regulatory impact review (RIR) and the initial regulatory flexibility analysis (IRFA) contained within the RIR, and the proposed rule through April 19, 1996.

**ADDRESSES:** Comments should be sent to Dr. Andrew A. Rosenberg, Director, NMFS, Northeast Regional Office, 1

Blackburn Drive, Gloucester, MA 01930. Mark the outside of the envelope "Comments on Multispecies Plan."

Comments regarding burden-hour estimates for collection-of- information requirements contained in this proposed rule should also be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, D.C. 20503 (Attention: NOAA Desk Officer).

Copies of proposed Amendment 7, its RIR and the IRFA contained within the RIR, and the Final Supplemental Environmental Impact Statement (FSEIS) are available from Douglas Marshall, Executive Director, New England Fishery Management Council, Suntaug Office Park, 5 Broadway (US Rte. 1), Saugus, MA 01906-1097.

**FOR FURTHER INFORMATION CONTACT:** Susan A. Murphy, Fishery Policy Analyst, 508-281-9252.

#### SUPPLEMENTARY INFORMATION:

Regulations implementing Amendment 5 to the FMP were published on March 1, 1994 (59 FR 9872). Amendment 5's principal objective was to eliminate the overfished condition of the multispecies finfish stocks. An emergency rule to further protect the severely depleted haddock resource was issued by NMFS and published January 3, 1994 (59 FR 26). This rule was extended through further rulemaking and permanently became effective with the publication of Secretarial Amendment 6 to the FMP (59 FR 32134).

Amendment 7 development began in response to an unprecedented report entitled, "Special Advisory: Groundfish Status on Georges Bank," issued and delivered by the Northeast Regional Stock Assessment Workshop to the New England Fishery Management Council (Council) at its August 9-10, 1994, meeting. The Advisory announced that Amendment 5 to the FMP is inadequate to achieve the reductions in fishing mortality rates needed to rebuild the principal groundfish stocks of cod, haddock and yellowtail flounder and cautioned that fishing mortality "should be reduced to as low a level as possible, approaching zero" to prevent further decline and to rebuild already collapsed stocks.

In response to this advice, the Council began development of Amendment 7 to the FMP. As an interim measure, the Council initiated, and NMFS approved, an emergency interim rule (59 FR 63926, December 12, 1994) to afford some additional protection to the multispecies resource during the development of Amendment 7. This emergency action was extended on March 13, 1995 (60 FR 13078). At the

request of the Council, NMFS approved Framework Adjustment 9 to the FMP (60 FR 19364, April 18, 1995) to implement measures contained in the emergency action on a permanent basis, until Amendment 7 could be finalized and implemented.

Recent scientific information from the Northeast Fisheries Science Center (NEFSC) confirms that groundfish stocks are at historical lows. Results from Stock Assessment Workshop 19 (SAW 19), presented to the Council at its February 15-16, 1995, meeting concluded that GOM cod continues to be overexploited and exhibits persisting low biomass levels. Stock assessment scientists counsel that spawning stock biomass decline for GOM cod should be halted and reversed immediately. Similarly, results from SAW 20 on GB haddock, presented at the August 10-11, 1995, Council meeting indicate that this stock remains in an overfished and collapsed condition and that fishing mortality needs to remain as low as possible.

In addition, the most recent U.S. and Canadian bottom trawl survey indices, through fall 1995 for GB and SNE yellowtail flounder and GB and GOM cod, indicate no significant new recruitment in any of these stocks and suggest a continuation of consistently low biomass levels. Overall, there is very little recruitment and very low biomass levels observed for all of these stocks and conservation of the vulnerable existing year classes has become critical. In the absence of immediate measures to husband older year classes and begin stock rebuilding, scientists caution that the recovery period may be substantially lengthened.

For haddock, both U.S. and Canadian survey results indicate a small amount of recruitment into the fishery, which, if mortality levels are kept low, may contribute to rebuilding these stocks.

#### Amendment 7

This Amendment would implement Alternative 3 of the Council's Amendment 7 public hearing document as refined and modified by the Council for adoption as its preferred alternative. The foundation of this action is an acceleration of the Amendment 5 effort-reduction schedule. This action would build and expand upon the current management system, serving as a basic structure to be further developed by the Council through the framework process.

#### Disapproved Measures

Three measures proposed in Amendment 7 have been disapproved by NMFS and are not included in this proposed rule. The allowance of

additional DAS for trawl vessels in the Individual DAS category that use 8-inch mesh; the 300-lb (136.1-kg) possession allowance of regulated species for trawl vessels that use 8-inch mesh in an exempted fishery; and the establishment of a Limited Access permit category for vessels that fished in the Possession Limit Open Access category under Amendment 5, have been determined to be inconsistent with the national standards of the Magnuson Fishery Conservation and Management Act (Magnuson Act) or other applicable law.

The first measure, which would grant additional DAS for large mesh trawl vessels, was proposed by the Council based on its policy to provide incentives for using mesh larger than the minimum size. The Council provided this incentive to trawl and gillnet vessels that would have received the Fleet category DAS allocation and to trawl vessels that would receive the Individual category DAS allocation, but did not provide it to the gillnet vessels that may be permitted in this category. This omission, whether intentional or unintentional, is inequitable; and was therefore disapproved, because it is inconsistent with Magnuson Act National Standard 4. Increased DAS for large mesh Fleet category vessels (both gillnet and trawls) was not disapproved, because no inequity is established within that category.

The 300-lb (136.1-kg) allowance of regulated species bycatch for vessels fishing in an exempted fishery (i.e., a fishery that has less than five-percent bycatch of regulated species) was disapproved, because it conflicts with the Council's proposed exempted fishery measure. A fishery can be exempted only if sufficient information is available to demonstrate that it would have a minimal bycatch of regulated species, otherwise the fishery is not allowed. The exemption standard is a strong disincentive against regulated species bycatch. The 300-lb (136.1-kg) allowance would provide an incentive for regulated species bycatch, counteracting the effect of the bycatch prevention measure. Therefore, because this measure would counteract the conservation effect of the bycatch protection measures, it cannot be reasonably calculated to promote conservation; therefore it is inconsistent with National Standard 4.

The proposed establishment of a new possession limit category was also disapproved. This category would establish an inequity and impose an undue administrative burden on NMFS. The Council set the possession limit for this category at zero, making it effectively more restrictive than the

open access categories. Thus, a vessel applying to fish in this category would be committing to at least one year without the ability to land regulated species. The administrative burden of establishing this category is likely to be significant due to the permit eligibility reviews and appeal process. The Amendment does not make clear the purpose of the category, that is, which sector of the industry would be served by it. This measure would present a significant administrative cost to NMFS with no discernable benefit or purpose.

The Council will have the opportunity to reconsider, modify, and possibly resubmit these measures under the Magnuson Act's 60-day accelerated review schedule.

#### Measures of Concern

Public comments are particularly sought on several measures. The first such measure is the possession allowance for the Open Access Handgear Category that would allow a directed fishery on multispecies with only a 300-lb (136.1-kg) constraint on cod, haddock and yellowtail catch and a requirement to use hand gear. Charter/Party permit holders and recreational vessels may obtain the Handgear permit, which raises enforcement concerns about determining which set of rules a vessel may be fishing under at any given time. A call-in requirement for Charter/Party vessels is proposed to aid in distinguishing which type of trip a vessel is conducting, but this would only provide a partial solution at the expense of complicating the DAS call-in program.

The second measure is the white hake exemption program presented in the Amendment as an option for future implementation by the Director, Northeast Regional, NMFS (Regional Director). This exemption would allow a directed fishery on a regulated species, white hake, outside the constraint of a DAS. This possible exemption raises concern as this fishery is currently fully exploited and may not be able to withstand additional pressure.

Third, the Large Mesh DAS permit, which would allocate additional DAS to vessels using mesh larger than the minimum size, is based on the notion that the selectivity of this mesh would compensate for the additional allocation of DAS. However, no mesh selectivity studies for 7- (17.8 cm) and 8-inch (20.3 cm) mesh in these fisheries exist yet.

Fourth, the Council proposed a change to the boundary for the Mid-Atlantic area to incorporate the inshore waters of New York. For the purposes of enforcement, the proposed rule simplifies the Council's definition of the

new boundary line by using fewer coordinates. The simplified definition would appear to achieve the Council's objective. This rule proposes to define the Mid-Atlantic regulated mesh area as the area bounded on the east by a line running from the Rhode Island shoreline along 71°47.5' W. long. to its intersection with the three-nautical mile line, south along the three-nautical mile line to Montauk Point, southwesterly along the three-nautical mile line to the intersection of 72°30' W. long., and south along that line to the intersection of the outer boundary of the EEZ (see Figure 1 to part 651).

Amendment 7 did not specifically exempt mid-water trawl gear from the proposed GOM area closures, but left open the possibility that this gear may become exempt in the future. NMFS is seeking public comment on this possibility.

Because Amendment 7 proposes to eliminate the DAS exemption for gillnet vessels, most gillnet vessels will become permitted in either the Fleet or the Individual DAS category. NMFS is seeking comment on how to calculate the number of DAS for any gillnet vessel that may appeal the number of Individual DAS assigned to it by NMFS because a vessel's initial allocation of DAS is currently based on time away from the dock and a gillnet DAS is proposed to be counted under this rule as time when gear is in the water.

Fifth, the Council proposed the allowance of a possession limit for winter flounder in the Mid-Atlantic regulated mesh area. NMFS is concerned about the impact of this, and the Winter Flounder State Waters exemptions because of the severely overfished status of this resource.

The following summarizes the remaining proposed measures.

#### Total Allowable Catch

The Amendment would establish a procedure for setting annual target TAC levels for specific cod, haddock, and yellowtail flounder stocks (GB cod, haddock, and yellowtail flounder, SNE yellowtail flounder, and GOM cod), and an aggregate TAC for the combined stocks of the other regulated species (pollock, redfish, white hake, witch flounder, American plaice, winter flounder and windowpane flounder). This procedure would be used annually to set TACs, with the exception of TACs for 1996, which would be set by this rule. The TACs would be set based on the best available scientific information and would provide a measure by which to evaluate the effectiveness of the management program and to make determinations on the need for

adjustments to this program on an annual basis. The TAC levels would be set so as to attain a fishing mortality rate that would allow cod, haddock, and yellowtail flounder stocks to rebuild over time, and to maintain current potential yield for the seven other regulated species.

The 1994 special advisory concluded that fishing mortality "should be reduced to as low a level possible, approaching zero" for GB stocks of cod, haddock and yellowtail flounder, and SNE yellowtail flounder. The biological reference point of  $F_{0.1}$  was selected by the Council as the most practicable way to achieve this goal, considering the needs of the fishery. For GOM cod, a biological reference point of  $F_{max}$  was selected because this stock is not as depleted as the others. TACs for the remaining regulated species would be set at levels corresponding to recent fishing mortality rates to ensure that effort is not redirected on these stocks. Because the Council's overriding management objective is to rebuild the five primary stocks of cod, haddock and yellowtail flounder, the management program established under Amendment 5, and expanded in this Amendment, is based on these primary stocks as well. In other words, the remaining multispecies stocks, other than cod, haddock and yellowtail flounder, would be protected under the management program developed for the primary stocks.

Using the 1993 fishing mortality rates contained in Amendment 5 as a baseline, an 80 percent average reduction in the fishing mortality rate is required to achieve the fishing mortality goals for the above mentioned stocks. This Amendment proposes to accomplish the reduction primarily through a combination of reductions in DAS, bycatch controls, area closures and elimination of previously established exemptions to effort reduction programs.

#### Specification of 1996 and 1997 TAC and Adjustments

For the period May 1, 1996, through April 30, 1997, the TAC levels that would correspond to the fishing mortality rate objectives are contained in the table below (calculation of the TACs is based on scientific assessment incorporating data and estimates of stock sizes, recruitment patterns, natural and fishing mortality, growth, etc.).

TABLE 1.—1996 TAC SPECIFICATIONS

Species	1996 target TACs (metric tons)
Georges Bank cod .....	1,851
Georges Bank haddock .....	2,801
Georges Bank yellowtail flounder .....	385
Gulf of Maine cod .....	2,761
Southern New England yellowtail flounder .....	150
Aggregate for remaining regulated species .....	25,500

Specification of TACs and adjustments for 1997 and beyond would be accomplished through the annual review framework process discussed later in this document.

#### Days-at-Sea Effort Control Program

The Amendment proposes to reduce DAS in two equal increments, on May 1, 1996 and May 1, 1997, to the level called for in the final year of the current Amendment 5 DAS reduction schedule. In addition, vessels previously exempted from the DAS program would be subject to the effort control program through this Amendment. Specifically, vessels in the 45-ft (13.7 m)-and-less, Hook-Gear and Gillnet Permit categories were exempted from the DAS program. Amendment 7 proposes to eliminate these exemptions and allocate DAS to all but the smallest group of vessels, those 30 ft (9.1 m) or less in length.

Existing limited access vessels subject to the effort-control program would continue under reduced DAS allocations. Vessels currently in the Individual and Combination DAS permit categories would have their DAS allocation reduced by 35 percent of their Amendment 5 baseline in fishing year 1996 and by 50 percent in fishing year 1997. Vessels assigned to the Fleet DAS limited access permit category would receive an allocation of 139 DAS in the fishing year 1996 and 88 DAS in the fishing year 1997.

Limited access vessels that agree to use sink gillnet gear with a minimum mesh size of 7 inches (17.8 cm) for the entire fishing year could opt to fish under a new permit category "Large Mesh DAS" and would be allocated 155 DAS in 1996, and 120 DAS in 1997. Similarly, trawl vessels choosing to fish exclusively with nets with a minimum mesh size of 8 inches (20.32 cm) when fishing under a groundfish DAS allocation could also enroll in this category and receive the same DAS allocation. Again, DAS allocations for 1997 may change as the result of the annual review process described under the framework provisions.

Limited access vessels 30 ft (9.1 m) or less in length that do not fish under a DAS program would be restricted to a cod, haddock and yellowtail flounder possession limit of up to a maximum combined weight of 300 lb (136.1 kg), but would not be subject to any limits on other multispecies finfish. These vessels may choose instead to fish under the DAS program. Vessels issued a 1995 valid limited access multispecies permit and fishing under the Small boat exemption (less than or equal to 45 ft (13.7 m)) that are 20 ft (6.1 m) or less in length, would initially be assigned to the Small Vessel (less than or equal to 30 ft (9.1 m)) category. However, due to different methods of measuring overall length, vessels greater than 20 ft (6.1 m) but less than or equal to 30 ft (9.1 m) would need to provide verification of overall length to obtain a Small Vessel category permit.

With the exception of one 20-consecutive-day block of time between March 1 through May 31 that all vessels subject to the effort-control program would be required to "take out" of the fishery, this rule would eliminate the Fleet DAS category requirement of taking blocks of time "out" of the multispecies fishery as well as the layover day provision currently required after completion of a multispecies DAS.

Upon implementation of this rule, DAS will be prorated to account for a full fishing year beginning May 1, 1996, through April 30, 1997.

#### Closed Areas

In addition to retaining the current closed areas, the Amendment would close additional areas, seasonally, to reduce further fishing mortality. The areas selected for closure correspond to the current time/area closures imposed on sink gillnet vessels in the GOM, that is, the Northeast Closure Area, the Mid-Coast Closure Area, and the Massachusetts Bay Closure Area to reduce the bycatch of harbor porpoise. These areas would be closed to all gear types capable of catching multispecies. By extending the closure of these areas to all gear capable of catching multispecies, the goal of reducing bycatch of harbor porpoise can be realized in a less complex and more enforceable manner, while at the same helping to achieve the goal of reducing fishing mortality for regulated species in the GOM. Further, because the closure areas range from the U.S.-Canadian boundary, down through Massachusetts Bay, and would be closed for different seasons and for relatively short periods of time, they would affect vessels more or less equally throughout the GOM region. All vessels would be allowed to

transit these areas, provided that their gear is properly stowed. To minimize the impact of these closures on other fisheries, gears that have little or no impact on regulated species would be exempt from the closures.

#### Exempted Fisheries

Under this proposed rule, vessels fishing in the GOM/GB and SNE regulated mesh areas would be allowed to fish only in an exempted fishery, under a DAS (multispecies or scallop), or under the small vessel category. An exempted fishery is one in which it has been determined that there is a minimal bycatch of regulated species. Currently, a five-percent standard is applied to fisheries utilizing mesh smaller than the minimum mesh size in the GOM, GB or SNE regulated mesh areas. This rule would extend the restriction to large mesh fisheries and would revise the requirement to reflect the Council's intent that the five-percent standard is an absolute maximum and that other restrictions on fishing gear and/or seasons may be considered to reduce bycatch.

#### Changes To Permit Categories

The Amendment would establish two additional limited access permit categories and allow some vessels in an open access category an opportunity to qualify for a limited access permit under specified criteria.

During the development of Amendment 5, the open access Hook-Gear category was promoted by the Council as the remaining opportunity for new entrants into the multispecies fishery. Under Amendment 7, vessels holding open access permits would no longer be allowed to target regulated species. Consequently, individuals that may have invested in vessels and gear based on the Council's guidance and that have participated in the fishery would be given an opportunity to qualify for a Hook-Gear limited access permit, if they meet the following criteria: The vessel held a 1995 open access Hook-Gear permit and submitted to the Regional Director, no later than January 26, 1996, fishing log reports dated between June 1, 1994 and June 1, 1995, documenting landings of at least 500 lb (226.8 kg) of multispecies finfish. Under Amendment 5 regulations, all vessels issued a multispecies permit are required to submit logbooks within 15 days after the end of each month. The January 26, 1996 deadline, therefore, actually is less restrictive than the current provision. Vessels fishing under the limited access Hook-Gear permit would be restricted to setting no more than 4,500 hooks per day. And finally,

vessels qualifying for the limited access Hook-Gear permit under this provision would be restricted to that limited access category and could not select a different limited access permit category.

A new limited access category also would be established for vessels that currently have limited access status and that choose to use larger than the minimum size mesh in exchange for an increased allocation of DAS. The mesh requirements for this category were described under "Days at Sea Effort Control Program."

Vessels 30 ft (9.1 m) or less in length that choose to fish under the Small Vessel permit category and vessels possessing an open access Handgear permit category would not be allowed to fish for, possess, or land regulated multispecies between March 1 and March 20 of each year.

This rule also proposes three new open access permit categories: Handgear, Charter/party and Scallop Multispecies Possession Limit. Vessels holding Handgear permits could possess, land, and sell up to 300 lb (136.1 kg), combined weight, of cod, haddock, and yellowtail flounder, and unlimited amounts of the other multispecies finfish, provided they use rod and reel or handlines only (no jigging machines). Charter/party permits would be required for vessels that carry passengers for hire and that do not possess a limited access permit. These vessels would be restricted by the recreational fishing provisions on minimum fish sizes, gear, and a prohibition on sale. Charter/party permit holders could also obtain an open access Handgear permit to fish commercially for multispecies finfish when they are not fishing under hire. Limited access scallop vessels could obtain an open access Scallop Multispecies Possession Limit permit and possess, land and sell up to 300 lb (136.1 kg) of regulated species when fishing under a scallop DAS.

#### Other Measures

The current experimental dogfish trawl fishery in the Nantucket Shoals area would be implemented on a permanent basis during the time period of June 1 through October 15 of each year. Extensive sea sampling conducted by the Massachusetts Division of Marine Fisheries has shown that this fishery has a very low bycatch of regulated species and is, therefore, an appropriate candidate for exemption to the mesh restrictions. Vessels participating in the Nantucket Shoals dogfish exemption program would be required to have on board an authorization letter issued by the Regional Director and would be

allowed to retain the bycatch species and amounts allowed in the GB/GOM small mesh exemption area, as well as skates in an amount up to 10 percent of other fish on board.

Limited access vessels would be allowed to continue fishing under the current state waters winter flounder exemption program. This program is available to vessels fishing in the waters of any state that is in compliance with the Atlantic States Marine Fisheries Commission's (ASMFC) Winter Flounder Fishery Management Program. Additionally, limited access vessels that are not fishing under the DAS program would be allowed to retain up to 500 lb (226.8 kg) of winter flounder when fishing under this exemption program.

Vessels fishing in the Mid-Atlantic regulated mesh area, when not fishing under a DAS, would be allowed to possess, land, and sell winter flounder up to 10 percent by weight of all other species on board, or 200 lb (90.72 kg), whichever is less.

Vessels fishing in the SNE regulated mesh area would be allowed to retain a bycatch of skate or skate parts up to 10 percent of the total weight of other fish possessed on board, when fishing under the small-mesh exemption provision. This possession limit represents a legitimate bycatch when fishing in the exempted species program, while eliminating the incentive to conduct a directed fishery on skate.

A provision would be added to the Observer Program section that would allow the Regional Director to accept observer coverage funded by sources other than NMFS, provided certain conditions are met. These conditions are: That all observer coverage is determined by NMFS to be in compliance with NMFS' sea-sampling guidelines and procedures; that the owner or operator of the vessel complies with all requirements under the multispecies plan; and that the observer is approved by the Regional Director.

Because the Small Mesh Area 1 exemption area lies entirely within the Mid-coast Closure Area, the season termination date for this exemption would be changed to coincide with the closure of this area. The current Small Mesh Area 1 season of July 15 through November 15 would, therefore, be changed to July 15 through October 31.

Amendment 7 requires that recreational and charter/party vessels comply with the following restrictions: A 20-inch (50.8-cm) minimum fish size for cod and haddock for the first year of the plan increasing to 21-inches (53.3 cm) in the second year; a prohibition on the sale of multispecies finfish; and a two hook-per-line limit for each angler.

In addition, there would be a 10 fish bag limit on cod and haddock, combined, for recreational anglers. This would not include charter/party vessels.

Charter/party vessels not fishing under the DAS program that possess limited access multispecies permits or open access Handgear permits would be required to fish under the recreational provisions, when fishing for hire.

Amendment 7 would expand the FMP's existing framework provision to remove the current 10-percent cap on annual reductions in fishing mortality and establish an annual process to review progress towards fishing mortality goals and to make changes in the management program, including recreational provisions. A Multispecies Monitoring Committee (MSMC) would be established to consist of technical staff from the New England and Mid-Atlantic Council's, the NMFS Northeast Regional Office, the NEFSC, and representatives from the U.S. Coast Guard, the fishing industry, and from affected coastal states appointed by the ASMFC. The MSMC would meet annually and, based on a review of the status of the resource, would recommend to the Multispecies Committee of the Council annual DAS adjustments by fleet sector, target TACs and any other management measure adjustments necessary to achieve the FMP's goals. After considering this recommendation, and any public comment, the Council would then make a recommendation to the Regional Director on annual TACs and adjustments to management measures, if any, for the following fishing year. If the Council fails to submit a recommendation to the Regional Director by February 1 that meets the FMP goals and objectives, the Regional Director may publish as a proposed rule one of the options reviewed and not rejected by the Council, provided that the option meets the FMP objective and is consistent with other applicable law. If, after considering public comment, the Regional Director decides to approve the option published as a proposed rule, the action will be published as a final rule in the Federal Register.

This rule would revise the current haddock possession limit to be 1,000 lb (453.6 kg) for vessels fishing under a multispecies DAS. Existing regulations limit possession of haddock to 500 lb (226.8 kg) or its equivalent, as measured by the volume of four standard boxes or five standard totes. This volumetric measure has, in practice, allowed vessels to land more than the 500-lb (226.8-kg) haddock trip limit because volumetric equivalent measures turned out to be too generous. This has made

enforcement of this provision problematic for cases based solely on landing records. Therefore, in response to the elimination of the use of this volumetric measure and to address that industry concern over vessels catching more than the 500-lb (226.8-kg) haddock trip limit and consequently discarding fish, the possession limit of haddock would be increased to 1,000 lb (453.6 kg). Although the status of haddock remains critical, other more restrictive conservation measures proposed under this plan would afford additional benefits to this species.

For clarity, Latin nomenclature for genus and species has been added to the Definitions section and removed from all other sections.

Unless changed by this proposed rule, all measures currently in place under the FMP would remain in effect.

#### Classification

This action has been determined to be economically significant for the purposes of E.O. 12866.

Section 304(a)(1)(D)(ii) of the Magnuson Act, as amended, requires NMFS to publish implementing regulations proposed by a Council within 15 days of the receipt of an amendment and proposed regulations. At this time, NMFS has not determined whether the amendment these rules would implement is consistent with the national standards, other provisions of the Magnuson Act, and other applicable law. NMFS, in making that determination, will take into account the information, views and comments received during the comment period.

The Council prepared a FSEIS for Amendment 7 describing the possible impacts on the environment as a result of this rule. This amendment is expected to have a significant impact on the human environment. A copy of the FSEIS may be obtained from the Council (see ADDRESSES).

The Biological Opinion (BO) for the original consultation on the initial FMP in 1986 concluded that the fishing activities resulting from that action may affect but are not likely to jeopardize the continued existence of endangered and threatened species of marine mammals, sea turtles, and fish or their critical habitat(s) found in the affected area. This conclusion was re-evaluated in a BO for the Marine Mammal Exemption Program MMEP initiated in 1989 under the Marine Mammal Protection Act of 1972. New information regarding incidental take was introduced and the conclusion of no jeopardy was reached. Amendment 5 to the FMP contained measures to reduce the incidental take of marine mammals and implemented

significant effort reduction measures. Due to the scope of the proposed amendment and the fact that right whale critical habitat has been designated since the BO for Amendment 5 to the Multispecies FMP was written, formal consultation was re-initiated. This consultation does not change the basis for the original determination. The consultation concluded that the provisions of the proposed amendment may affect but are not likely to jeopardize the continued existence of endangered and threatened species or their critical habitat(s).

Adverse impacts on marine mammals resulting from fishing activities conducted under this rule are discussed in the FSEIS.

In compliance with the Regulatory Flexibility Act, the Council has prepared an IRFA as part of the RIR contained in Amendment 7 that concludes that this proposed rule would have significant economic impacts on a substantial number of small entities. The measures proposed are restrictive, and impacts on the industry are expected to be significant. In the early years of the program, some vessels may be unable to cover their costs, in part because of these restrictions and also due to the poor condition of the stocks. Such vessels are expected to leave the fishery. Relative to the status quo, however, this proposal produces positive significant effects on a substantial number of small entities after stock abundance of groundfish recovers. The majority of the vessels in the Northeast Multispecies Fishery are considered small entities. The proposed action will reduce the overall revenues of the multispecies industry by approximately 10 to 25 percent in the first three years of the program compared to the status quo. The impact of the proposed action will not be uniform for all vessels or all sectors. Instead, the action will have different effects on different gear groups, with trawlers being relatively more disadvantaged than other vessels. This is primarily because trawlers produce the largest share of total groundfish landings and have higher costs. Alternately, smaller independent vessels are well suited to adapting to year to year changes in species as availability changes. Generally, smaller vessels are more flexible and have lower costs. The proposed action would allow vessels 30 ft (9.1 m) or less in length to be exempt from the DAS program, provided they comply with the 300-lb (136.1-kg) cod, haddock, and yellowtail flounder possession limit. Cod, haddock, and yellowtail flounder

comprise 15 percent of the revenue of these vessels.

The negative effects of the non-selected alternatives would be greater than those of the proposed measures. Expected impacts of the proposed action on crew income are negative in the first 5 years of the program and positive thereafter. Likewise, the level of employment is expected to decline in the short-term to an undetermined extent but will rebound over the long term. Projected revenues from fishing will be positive beginning in the year 2001, which will create demand for other goods and services in the area and lead to increased production and employment. The overall impacts will be positive. The proposed action is expected to increase net benefits to the nation by \$18 million over the 10-year rebuilding period. The recreational sector is not expected to be negatively impacted by this action.

The proposed action is economically significant for the purposes of E.O. 12866, but probably will not have an annual impact on the economy of \$100 million or more, and will not adversely affect the productivity, environment, public health or safety or state, local or tribal governments or communities in the long term. By increasing multispecies catch rates in the long term and reducing operating costs, the proposed action is expected to make the industry more productive after recovery of groundfish stock abundance and to increase the competitiveness of the domestic industry in comparison to foreign suppliers.

This proposed rule contains six new collection-of-information requirements subject to the Paperwork Reduction Act and have been submitted to OMB for approval. The public reporting burden for these collection-of-information requirements are indicated in the parentheses in the following statements and include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this reporting burden estimate or any other aspect of the collection of information, including suggestions for reducing the burden, to NMFS and OMB (see ADDRESSES).

The new requirements are:

1. The Nantucket Shoals Dogfish exemption, OMB# 0648-0202, will require vessel notification (2 minutes/response).

Revisions to the existing requirements are:

2. Proof of VTS installation, OMB# 0648-0202, (2 minutes/response);

3. Call-in or card system, OMB# 0648-0202, (2 minutes/response);

4. Limited access permit, OMB# 0648-0202. Appeal of the DAS allocation will require written submission (2 hours/response);

5. Limited access permit appeals, OMB# 0648-0202, appeal of denied permits will require written submission (0.5 hours/response);

6. Three new vessel permit categories (Handgear, Charter/Party and Scallop Multispecies Possession Limit), OMB# 0648-0202, are created with no increase in burden above that currently associated with vessel permits.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number.

#### List of Subjects in 50 CFR Part 651

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: February 26, 1996.

Gary Matlock,

Program Management Officer, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 651 is proposed to be amended as follows:

#### PART 651—NORTHEAST MULTISPECIES FISHERY

1. The authority citation for part 651 continues to read as follows:  
Authority: 16 U.S.C. 1801 *et seq.*

2. In § 651.2, the definition for "Charter and party boats" is removed, and the definitions for "Alewife", "American shad", "Atlantic croaker", "Black sea bass", "Blowfish", "Bluefish", "Charter or party boat or charter/party boat", "Conger eels", "Cunner", "Dogfish", "Exempted gear", "Fourspot flounder", "Hagfish", "Handgear", "Handline or handline gear", "Hickory shad", "John Dory", "Longhorn sculpin", "Mullet", "Multispecies Monitoring Committee", "Rod and reel", "Scup", "Sea raven", "Searobin", "Skate", "Spot", "Summer flounder", "Swordfish", "Target Total Allowable Catch (TAC)", "Tautog", "Tilefish", and "Weakfish" are added, in alphabetical order; the definitions for "DAS (Days-at-sea)", "Out of the multispecies fishery or DAS program", and "Sink gillnet" are revised to read as follows:

#### § 651.2 Definitions.

\* \* \* \* \*

*Alewife* means *Alosa pseudoharengus*.

\* \* \* \* \*

*American shad* means *Alosa sapidissima*.

*Atlantic croaker* means *Micropogonias undulatus*.

\* \* \* \* \*

*Black sea bass* means *Centropristis striata*.

*Blowfish* (puffer) means any species in the family *Tetraodontidae*.

*Bluefish* means *Pomatomus saltatrix*.

\* \* \* \* \*

*Charter or party boat or charter/party boat* means any vessel carrying passengers for hire to engage in recreational fishing and that is not fishing under a DAS.

\* \* \* \* \*

*Conger eels* means *Conger oceanicus*.

\* \* \* \* \*

*Cunner* means *Tautoglabrus adspersus*.

*DAS (Days-at-sea)* means the 24-hour periods of time during which a fishing vessel is absent from port in which the vessel intends to fish for, possess or land, or fishes for, possesses, or lands regulated species, or for gillnet vessels, the 24-hour periods of time beginning when the gillnet vessel leaves port with the intent to fish for, possess or land, or fishes for, possesses or lands regulated species, and ending when a gillnet vessel returns to port with all of its gillnet gear that was in the water on board.

\* \* \* \* \*

*Dogfish* means spiny dogfish, *Squalus acanthias*, or smooth dogfish, *Mustelus canis*.

\* \* \* \* \*

*Exempted gear* means gear that is deemed to be not capable of catching multispecies finfish and includes: pelagic hook and line, pelagic longline, spears, rakes, diving gear, cast nets, tongs, harpoons, weirs, dipnets, stop nets, pound nets, pelagic gillnets, pots and traps, purse seines, shrimp trawls (with a properly configured grate as defined under this part), and mid-water trawls.

\* \* \* \* \*

*Fourspot flounder* means *Paralichthys oblongus*.

\* \* \* \* \*

*Hagfish* means *Myxine glutinosa*.

*Handgear* means handline or rod and reel gear.

*Handline or handline gear* means fishing gear that is released by hand and consists of one main line to which is attached up to two leaders for a total of



not more than three hooks. Handlines are retrieved only by hand, not by mechanical means.

\* \* \* \* \*

*Hickory shad* means *Alosa mediocris*.

\* \* \* \* \*

*John Dory* means *Zenopsis conchifera*.

\* \* \* \* \*

*Longhorn sculpin* means  
*Myoxocephalus octodecimspinosus*.

\* \* \* \* \*

*Mullet* means any species in the family *Mugilidae*.

\* \* \* \* \*

*Multispecies Monitoring Committee* means a team of scientific and technical staff appointed by the Council to review, analyze, and recommend adjustments to the management measures. The team will consist of staff from the New England and Mid-Atlantic Fishery Management Councils, the NMFS Northeast Regional Office, the NEFSC, the U.S. Coast Guard, an industry representative, and representatives from affected coastal states appointed by the Atlantic States Marine Fisheries Commission.

\* \* \* \* \*

*Out of the multispecies fishery or DAS program* means the period of time during which a vessel is absent from port and is not fishing for regulated species under the multispecies DAS program.

\* \* \* \* \*

*Rod and reel* means a hand-held (including rod holder) fishing rod with a manually operated reel attached.

\* \* \* \* \*

*Scup* means *Stenotomus chrysops*.

*Sea raven* means *Hemitripterus americanus*.

*Searobin* means any species in the family *Triglidae*.

*Sink gillnet* means a bottom-tending gillnet, which is any gillnet, anchored or otherwise, that is designed to be, or is fished on or near the bottom in the lower third of the water column.

*Skate* means any species in the family *Rajidae*.

*Spot* means *Leiostomus xanthurus*.

\* \* \* \* \*

*Summer flounder* means *Paralichthys dentatus*.

*Swordfish* means *Xiphias gladius*.

*Target Total Allowable Catch (TAC)* means the annual domestic harvest targets for regulated species.

*Tautog* (blackfish) means *Tautoga onitis*.

\* \* \* \* \*

*Tilefish* means *Lopholatilus chamaeleonticeps*.

\* \* \* \* \*

*Weakfish* means *Cynoscion regalis*.

\* \* \* \* \*

3. In § 651.4, paragraphs (a), (b), (c), (e), (f), (h)(1)(ii), (h)(1)(iii) and (q) are revised to read as follows:

#### § 651.4 Vessel permits.

\* \* \* \* \*

(a) *General*. Any vessel of the United States, including a charter or party boat, must have been issued and have on board a valid Federal multispecies permit issued under this part to fish for, possess or land multispecies finfish in or from the EEZ. Recreational vessels and vessels fishing for multispecies exclusively in state waters are exempt from this requirement.

(b) *Limited access permits*—(1) *Eligibility*—

(i) *Limited access multispecies permit*. To be eligible for a multispecies limited access permit, specified in § 651.22, in 1996 and thereafter, a vessel must have been issued a limited access multispecies permit for the preceding year, must be replacing a vessel that was issued a limited access multispecies permit for the preceding year, or must qualify for a 1996 limited access multispecies permit under paragraph (b)(1)(ii) of this section.

(ii) *Limited access hook-gear permit*. A vessel issued a 1995 open access hook-gear permit may apply for and obtain a 1996 limited access hook-gear permit provided it meets the criteria for eligibility described below. Vessels must apply for a limited access Hook-Gear permit before September 1, 1996, to receive an automatic mailing of an application to renew their permit in 1997 and to be insured that their permit application will be processed within the 30 days allowed under paragraph (e) of this section. Vessels applying after December 31, 1996, will be ineligible to apply for a 1997 limited access hook-gear permit. A vessel qualifying for a limited access hook-gear permit may not change its limited access permit category. The criteria for eligibility are:

(A) The vessel held a 1995 open access Hook-Gear permit and submitted to the Regional Director, no later than January 26, 1996, fishing log reports dated between June 1, 1994 and June 1, 1995, documenting landings of at least 500 lb (226.8 kg) of multispecies finfish; or

(B) The vessel is replacing a vessel that meets the criteria set forth in paragraph (b)(1)(ii)(A) of this section.

(2) *Qualification restriction*. Unless the Regional Director determines to the contrary, no more than one vessel may qualify, at any one time, for a limited access multispecies permit based on that or another vessel's fishing and

permit history. If more than one vessel owner claims eligibility for a limited access multispecies permit, based on one vessel's fishing and permit history, the Regional Director shall determine who is entitled to qualify for the limited access multispecies permit and the DAS allocation according to paragraph (b)(3) of this section.

(3) *Change in ownership*. The fishing and permit history of a vessel is presumed to transfer with the vessel whenever it is bought, sold, or otherwise transferred, unless there is a written agreement, signed by the transferor/seller and transferee/buyer, or other credible written evidence, verifying that the transferor/seller is retaining the vessel's fishing and permit history for purposes of replacing the vessel.

(4) *Replacement vessels*. To be eligible for a limited access permit under this section, the replacement vessel must meet the following criteria and any applicable criteria under paragraph (b)(5) of this section:

(i) The replacement vessel's horsepower may not exceed by more than 20 percent the horsepower of the vessel that was initially issued a limited access multispecies permit as of the date the initial vessel applied for such permit; and

(ii) The replacement vessel's length, gross registered tonnage, and net tonnage may not exceed by more than 10 percent the length, gross registered tonnage, and net tonnage of the vessel that was initially issued a limited access multispecies permit as of the date the initial vessel applied for such permit. For purposes of this paragraph, a vessel not required to be documented under title 46, U.S.C. will be considered to be 5 net tons. For undocumented vessels, gross registered tonnage does not apply.

(5) *Upgraded vessel*. To remain eligible to retain a valid limited access permit under this part, or to apply for or renew a limited access permit under this part, a vessel may be upgraded, whether through refitting or replacement, only if the upgrade complies with the following limitations:

(i) The vessel's horsepower may be increased, whether through refitting or replacement, only once. Such an increase may not exceed 20 percent of the horsepower of the vessel initially issued a limited access multispecies permit as of the date the initial vessel applied for such permit; and

(ii) The vessel's length, gross registered tonnage, and net tonnage may be upgraded, whether through refitting or replacement, only once. Such an increase shall not exceed 10 percent each of the length, gross registered



tonnage, and net tonnage of the vessel initially issued a limited access multispecies permit as of the date the initial vessel applied for such permit. This limitation allows only one upgrade, at which time any or all three specifications of vessel size may be increased. This type of upgrade may be done separately from an engine horsepower upgrade.

(6) *Consolidation restriction.* Limited access permits under this permit and DAS allocations may not be combined or consolidated.

(7) *Appeal of denial of limited access multispecies permit.*

(i) Any applicant eligible to apply for an initial limited access Hook-Gear permit who is denied such permit may appeal the denial to the Regional Director within 30 days of the notice of denial. Any such appeal must be based on one or more of the following grounds, must be in writing, and must state the grounds for the appeal:

(A) The information used by the Regional Director was based on mistaken or incorrect data;

(B) The applicant was prevented by circumstances beyond his/her control from meeting relevant criteria; or

(C) The applicant has new or additional information.

(ii) The Regional Director will appoint a designee who will make the initial decision on the appeal.

(iii) The appellant may request a review of the initial decision by the Regional Director by so requesting in writing within 30 days of the notice of the initial decision. If the appellant does not request a review of the initial decision within 30 days, the initial decision shall become the final administrative action of the Department of Commerce.

(iv) Upon receiving the findings and a recommendation, the Regional Director will issue a final decision on the appeal. The Regional Director's decision is the final administrative action of the Department of Commerce.

(v) Status of vessels pending appeal of a limited access permit denial. A vessel denied a limited access Hook-Gear permit may fish under the limited access Hook-Gear category, provided that the denial has been appealed, the appeal is pending, and the vessel has on board a letter from the Regional Director authorizing the vessel to fish under the limited access Hook-Gear category. The Regional Director will issue such a letter for the pendency of any appeal. Any such decision is the final administrative action of the Department of Commerce on allowable fishing activity pending a final decision on the appeal. The authorizing letter must be carried on

board the vessel. If the appeal is finally denied, the Regional Director shall send a notice of final denial to the vessel owner; the authorizing letter becomes invalid 5 days after receipt of the notice of denial.

(8) *Limited access permit restrictions.*

(i) A vessel may be issued a limited access multispecies permit in only one category during a fishing year. Vessels are prohibited from changing limited access multispecies permit categories during the fishing year, except as provided in paragraph (f)(3) of this section. A vessel issued a limited access Hook-Gear permit may not change its limited access permit category at any time.

(ii) With the exception of Combination Vessels, sea scallop dredge vessels are prohibited from being issued a limited access multispecies permits.

(9) *Confirmation of Permit History.*

Notwithstanding any other provisions of this part, a person who does not currently own a fishing vessel, but who has owned a qualifying vessel that has sunk, been destroyed, or transferred to another person, may apply for and receive a Confirmation of Permit History if the fishing and permit history of such vessel has been retained lawfully by the applicant. To be eligible to obtain a Confirmation of Permit History, the applicant must show that the qualifying vessel meets the eligibility requirements, as applicable, in this part. Issuance of a valid and current Confirmation of Permit History preserves the eligibility of the applicant to apply for or renew a limited access multispecies permit for a replacement vessel based on the qualifying vessel's fishing and permit history at a subsequent time, subject to the replacement provisions specified at § 651.4. A Confirmation of Permit History must be applied for and received on an annual basis in order for the applicant to preserve the fishing rights and limited access eligibility of the qualifying vessel. If fishing privileges have been assigned or allocated previously under this part based on the qualifying vessel's fishing and permit history, the Confirmation of Permit History also preserves such fishing privileges. Any decision regarding the issuance of a Confirmation of Permit History for a qualifying vessel that has applied for or been issued previously a limited access permit under this part is a final agency action subject to judicial review under 5 U.S.C. 704. Applications for a Confirmation of Permit History must be received by the Regional Director by the beginning of the fishing year for which the Confirmation of Permit History is

required. Information requirements for the Confirmation of Permit History application shall be the same as those for a limited access permit with any request for information about the vessel being applicable to the qualifying vessel that has been sunk, destroyed or transferred. Vessel permit applicants who have been issued a Confirmation of Permit History and who wish to obtain a vessel permit for a replacement vessel based upon the previous vessel history may do so pursuant to paragraph (b)(4) of this section.

(c) *Open access permits.* Subject to the restrictions in § 651.33, a U. S. vessel that has not been issued a limited access multispecies permit may obtain an open access Handgear or Charter/party permit. Vessels that are issued a valid scallop limited access permit under § 650.4 of this chapter and that have not been issued a limited access multispecies permit may obtain an open access Scallop Multispecies Possession Limit permit.

\* \* \* \* \*

(e) *Vessel permit application.*

Applicants for a permit under this section must submit a completed application on an appropriate form obtained from the Regional Director. The application must be signed by the owner of the vessel, or the owner's authorized representative, and be submitted to the Regional Director at least 30 days before the date on which the applicant desires to have the permit made effective. The Regional Director will notify the applicant of any deficiency in the application pursuant to this section. Applicants for limited access multispecies permits shall provide information with the application sufficient for the Regional Director to determine whether the vessel meets the eligibility requirements specified.

(f) *Information requirements.* (1) In addition to applicable information required to be provided by paragraph (e) of this section, an application for a permit must contain at least the following information, and any other information required by the Regional Director: Vessel name; owner name, mailing address, and telephone number; U.S. Coast Guard documentation number and a copy of the vessel's current U.S. Coast Guard documentation or, if undocumented, state registration number and a copy of the current state registration; party/charter boat license; home port and principal port of landing; length overall; gross tonnage; net tonnage; engine horsepower; year the vessel was built; type of construction; type of propulsion; approximate fish-

hold capacity; type of fishing gear used by the vessel; number of crew; number of party or charter passengers licensed to carry (if applicable); permit category; if the owner is a corporation, a copy of the current Certificate of Incorporation, or other corporate papers showing incorporation and the names of the current officers in the Corporation, and the names and addresses of all shareholders owning 25 percent or more of the corporation's shares; if the owner is a partnership, a copy of the current Partnership Agreement and the names and addresses of all partners; if there is more than one owner, names of all owners owning a 25 percent interest or more; and, name and signature of the owner or the owner's authorized representative.

(2) Applications for an initial limited access Hook-Gear permit must also contain the following information:

(i) If the engine horsepower was changed or a contract to change the engine horsepower had been entered into prior to May 1, 1996, such that it is different from that stated in the vessel's most recent application for a Federal Fisheries Permit before May 1, 1996, sufficient documentation to ascertain the different engine horsepower. However, the engine replacement must be completed within one year of the date of when the contract for the replacement engine was signed.

(ii) If the length, gross tonnage, or net tonnage was changed or a contract to change the length, gross tonnage or net tonnage had been entered into prior to May 1, 1996, such that it is different from that stated in the vessel's most recent application for a Federal Fisheries Permit, sufficient documentation to ascertain the different length, gross tonnage or net tonnage. However, the upgrade must be completed within one year from the date when the contract for the upgrade was signed.

(3) A vessel issued a limited access multispecies permit may request a change in permit category, unless otherwise restricted by paragraph (b)(8) of this section. In 1996, any such change must be requested by submitting an application to the Regional Director within 45 days of implementation of this rule. After 45 days, the vessel must fish only in the DAS program assigned for the remainder of the 1996 fishing year. Any DAS that a vessel uses prior to a change in permit category will be counted against its allocation received under any subsequent permit category. For 1997 and beyond, limited access multispecies vessels eligible to request a change in permit category must elect a

category prior to the start of each fishing year and must remain in that permit category for the duration of the fishing year. A vessel issued an open access permit may request a different open access permit category by submitting an application to the Regional Director at any time.

(4) If the vessel is a combination vessel, or if the applicant elects to take an Individual DAS allocation or to use a VTS unit, although not required, a copy of the vendor installation receipt from a NMFS-certified VTS vendor as described in § 651.28(a).

\* \* \* \* \*

(h) \* \* \*

(i) \* \* \*

(ii) The application was not received by the Regional Director by the deadlines set forth in paragraphs (b)(1)(ii), and (q) of this section; or

(iii) The applicant and applicant's vessel failed to meet all eligibility requirements described in paragraph (b)(1) of this section; or

\* \* \* \* \*

(q) *Limited access multispecies permit renewal.* To renew or apply for a limited access multispecies permit a completed application must be received by the Regional Director by the first day of the fishing year for which the permit is required. Failure to renew a limited access multispecies permit in any year bars the renewal of the permit in subsequent years.

\* \* \* \* \*

4. Section 651.9 is revised to read as follows:

#### **§ 651.9 Prohibitions.**

(a) In addition to the general prohibitions specified in § 620.7 of this chapter, it is unlawful for any person owning or operating a vessel issued a valid Federal multispecies vessel permit issued under this part, issued a permit under § 651.5 or a letter under § 651.4(b)(7)(v), to do any of the following:

(1) Fail to report to the Regional Director within 15 days any change in the information contained in the permit application as required under § 651.4(m) or § 651.5(k).

(2) Fish for, possess, or land multispecies finfish unless the operator of the vessel has been issued an operator's permit under § 651.5, and a valid permit is on board the vessel.

(3) Sell, barter, trade, or transfer, or attempt to sell, barter, trade, or transfer to a dealer any multispecies finfish unless the dealer has a valid Federal dealer's permit issued under § 651.6.

(4) Sell, barter, trade, or transfer, or attempt to sell, barter, trade, or

otherwise transfer, for a commercial purpose, other than transport, any multispecies, unless the transferee has a dealer permit issued under § 651.6.

(5) Fail to comply in an accurate and timely fashion with the log report, reporting, record retention, inspection, and other requirements of § 651.7(b).

(6) Fail to affix and maintain permanent markings as required by § 651.8.

(7) Enter, fail to remove gear from, or be in the areas described in § 651.21(f)(1) through § 651.21(h)(1) during the time period specified, except as provided in § 651.21(d), (f)(2), (g)(2), and (h)(2).

(8) Possess or land multispecies finfish smaller than the minimum sizes specified in § 651.23 or § 651.34, as appropriate.

(9) Land, or possess on board a vessel, more than the possession limits specified in § 651.27(a), or violate any of the other provisions of § 651.27.

(10) Land, offload, remove, or otherwise transfer, or attempt to land, offload, remove, or otherwise transfer fish from one vessel to another vessel or other floating conveyance unless authorized in writing by the Regional Director pursuant to § 651.30(a).

(11) Refuse or fail to carry an observer if requested to do so by the Regional Director.

(12) Interfere with or bar by command, impediment, threat, coercion, or refusal of reasonable assistance, an observer conducting his or her duties aboard a vessel.

(13) Fail to provide an observer with the required food, accommodations, access, and assistance, specified in § 651.31.

(b) In addition to the prohibitions specified in paragraph (a) of this section, it is unlawful for any person owning or operating a vessel issued a limited access multispecies permit under § 651.4(b) or a letter under § 651.4(b)(7)(v), to do any of the following:

(1) Fish for, possess, or land multispecies finfish with or from a vessel that has had the horsepower of such vessel or its replacement upgraded or increased in excess of the limitations specified in § 651.4(b)(4) or § 651.4(b)(5).

(2) Fish for, possess, or land multispecies finfish with or from a vessel that has had the length, gross registered tonnage, or net tonnage of such vessel or its replacement increased or upgraded in excess of limitations specified in § 651.4(b)(4) or § 651.4(b)(5).

(3) Combine, transfer, or consolidate DAS allocations.

(4) Fish for, possess at any time during a trip, or land per trip more than the possession limit of regulated species specified in § 651.27(c) after using up the vessel's annual DAS allocation or when not participating under the DAS program pursuant to § 651.22, unless otherwise exempted under §§ 651.22(b)(3) or 651.34.

(5) Possess or land per trip more than the possession limit specified under § 651.22(b)(3)(i) if the vessel has been issued a limited access Small Vessel permit.

(6) Fail to comply with the restrictions on fishing and gear specified in § 651.22(b)(4) if the vessel has been issued a limited access Hook-Gear permit.

(7) Fail to declare and be out of the multispecies fishery as required by § 651.22(g), using the procedure described under § 651.22(h), as applicable.

(8) Land, or possess on board a vessel, more than the possession limit of winter flounder specified in § 651.27(b), or violate any of the other provisions specified in § 651.27(b).

(9) If required to have a VTS unit specified in § 651.28(a) or § 651.29(a):

(i) Fail to have a certified, operational, and functioning VTS unit that meets the specifications of § 651.28(a) on board the vessel at all times.

(ii) Fail to comply with the notification, replacement, or any other requirements regarding VTS usage specified in § 651.29(a).

(10) Fail to comply with any requirement regarding the DAS notification specified in § 651.29(a) or § 651.29(b).

(11) Fail to comply with other notification requirements, including a call-in system specified in § 651.29(c), if required by the Regional Director.

(12) Fail to provide notification of the beginning or ending of a trip, as required under § 651.29(b) and § 651.29(d).

(c) In addition to the prohibitions specified in paragraph (a) of this section, it is unlawful for any person owning or operating a vessel issued a Handgear permit under § 651.4(c) to do any of the following:

(1) Possess at any time during a trip, or land per trip, more than the possession limit of regulated species specified in § 651.33(a), unless the regulated species were harvested by a charter or party vessel.

(2) Use, or possess on board, gear capable of harvesting multispecies finfish other than rod and reel or handline while in possession of, or fishing for, multispecies finfish.

(3) Possess or land multispecies finfish during the time period specified in § 651.33(a)(2).

(d) In addition to the prohibitions specified in paragraph (a) of this section, it is unlawful for any person owning or operating a vessel issued a Scallop Multispecies Possession Limit permit under § 651.4(c) to do any of the following:

(1) Possess or land more than the possession limit of regulated species specified in § 651.33(c).

(2) Possess or land regulated species when not fishing under a scallop DAS.

(e) In addition to the general prohibitions specified in § 620.7 of this chapter and the prohibitions specified in paragraphs (a) through (d) of this section, it is unlawful for any person to do any of the following:

(1) Fish for, possess, or land multispecies finfish unless: (i) The multispecies finfish were being fished for or harvested by a vessel issued a valid Federal multispecies permit under this part, or a letter under § 651.4(b)(7)(v), and the operator aboard such vessel was issued an operator's permit under § 651.5 and a valid permit is on board the vessel;

(ii) The multispecies finfish were harvested by a vessel not issued a Federal multispecies permit that fishes for multispecies finfish exclusively in state waters; or

(iii) The multispecies finfish were harvested by a recreational fishing vessel.

(2) Sell, barter, trade, or otherwise transfer, or attempt to sell, barter, trade, or otherwise transfer, for a commercial purpose, any multispecies finfish from a trip unless the vessel is issued a valid Federal multispecies permit under this part, or a letter under § 651.4(b)(7)(v), and is not fishing under the charter/party restrictions specified in § 651.34(d), or unless the multispecies finfish were harvested by a vessel that qualifies for the exception specified in paragraph (e)(1)(ii) of this section.

(3) To be or act as an operator of a vessel fishing for or possessing multispecies finfish in or from the EEZ, or issued a Federal multispecies permit under this part, without having been issued and possessing a valid operator's permit issued under § 651.5.

(4) Purchase, possess, or receive for a commercial purpose, or attempt to purchase, possess, or receive for a commercial purpose in the capacity of a dealer, multispecies finfish taken from a fishing vessel, unless in possession of a valid dealer permit issued under § 651.6; except that this prohibition does not apply to multispecies finfish taken from a vessel that qualifies for the

exception specified in paragraph (e)(1)(ii) of this section.

(5) Purchase, possess, or receive for a commercial purpose or attempt to purchase, possess, or receive multispecies finfish caught by a vessel other than one issued a valid Federal multispecies permit under this part, or a letter under § 651.4(b)(7)(v), unless the multispecies finfish were harvested by a vessel that qualifies for the exception specified in paragraph (e)(1)(ii) of this section.

(6) Land, offload, cause to be offloaded, sell, or transfer; or attempt to land, offload, cause to be offloaded, sell, or transfer multispecies finfish from a fishing vessel, whether on land or at sea, as an owner or operator without accurately preparing and submitting, in a timely fashion, the documents required by § 651.7, unless the multispecies finfish were harvested by a vessel that qualifies for the exception specified in paragraph (e)(1)(ii) of this section.

(7) Purchase or receive multispecies finfish, or attempt to purchase or receive multispecies finfish, whether on land or at sea, as a dealer without accurately preparing, submitting in a timely fashion, and retaining the documents required by § 651.7.

(8) Possess or land fish caught with nets of mesh smaller than the minimum size specified in § 650.20 of this chapter, or with scallop dredge gear, unless said fish are caught, possessed or landed in accordance with § 651.20, or unless the vessel qualifies for the exception specified in paragraph (e)(1)(ii) of this section.

(9) Fish with, use, or have on board, within the area described in § 651.20(a)(1) nets of mesh size smaller than the minimum mesh size specified in § 651.20(a)(2), except as provided in § 651.20(a)(3) through (a)(6), (a)(8), (a)(9), (e), (f) and (j), or unless the vessel qualifies for the exception specified in paragraph (e)(1)(ii) of this section.

(10) Fish for, harvest, possess, or land in or from the EEZ northern shrimp, unless such shrimp were fished for or harvested by a vessel meeting the requirements specified in § 651.20(a)(3).

(11) Fish within the areas described in § 651.20(a)(4) with nets of mesh smaller than the minimum size specified in § 651.20(a)(2), unless the vessel is issued and possesses on board the vessel an authorizing letter issued under § 651.20(a)(4)(i).

(12) Violate any provisions of the Cultivator Shoals Whiting Fishery specified in § 651.20(a)(4).

(13) Fail to comply with the requirements of § 651.20(a)(5).

(14) Fail to comply with the requirements of § 651.20(a)(8).

(15) Fail to comply with the requirements of § 651.20(a)(9).

(16) Fish with, use, or have available for immediate use within the area described in § 651.20(c)(1) nets of mesh size smaller than the minimum size specified in § 651.20(c)(2), except as provided in § 651.20(c)(3), (e), (f), and (j), or unless the vessel qualifies for the exception specified in paragraph (e)(1)(ii) of this section.

(17) Fish with, use, or have available for immediate use within the area described in § 651.20(d)(1) nets of mesh size smaller than the minimum size specified in § 651.20(d)(2), except as provided in § 651.20(d)(3), § 651.20(e), § 651.20(f), and § 651.20(j), or unless the vessel qualifies for the exception specified in paragraph (e)(1)(ii) of this section.

(18) Fish for the species specified in § 651.20 (e) or (f) with a net of mesh size smaller than the applicable mesh size specified in § 651.20(a)(2), § 651.20(c)(2) or § 651.20(d)(2), or possess or land such species, unless the vessel is in compliance with the requirements specified in § 651.20(e) or § 651.20(f), or unless the vessel qualifies for the exception specified in paragraph (e)(1)(ii) of this section.

(19) Obstruct or constrict a net as described in § 651.20(h)(1) and § 651.20(2).

(20) Fish for, land, or possess multispecies finfish harvested by means of pair trawling or with pair trawl gear, except under the provisions of § 651.20(e), or unless the vessels that engaged in pair trawling qualify for the exception specified in paragraph (e)(1)(ii) of this section.

(21) Violate any of the restrictions on fishing with scallop dredge gear specified in § 651.20(i).

(22) Violate any of the provisions of § 651.20(j).

(23) Enter or be in the area described in § 651.21(a)(1) on a fishing vessel, except as provided in § 651.21(a)(2) and § 651.21(d).

(24) Enter or be in the area described in § 651.21(b)(1) on a fishing vessel, except as provided in § 651.21(b)(2).

(25) Enter or be in the area described in § 651.21(c)(1), on a fishing vessel, except as provided in § 651.21(c)(2) and § 651.21(d).

(26) Enter or be on a fishing vessel, or fail to remove gear from the EEZ portion of the areas described in § 651.21(f)(1) through § 651.21(h)(1), during the time period specified, except as provided in § 651.21(d), § 651.21(f)(2), § 651.21(g)(2), and § 651.21(h)(2).

(27) Import, export, transfer, land, buy, sell or possess regulated species smaller than the minimum sizes specified in § 651.23, unless the regulated species were harvested from a vessel that qualifies for the exception specified in paragraph (e)(1)(ii) of this section.

(28) Violate any terms of a letter authorizing experimental fishing pursuant to § 651.24 or fail to keep such letter on board the vessel during the period of the experiment.

(29) Fail to comply with the gear-marking requirements of § 651.25.

(30) Purchase, possess, or receive as a dealer, or in the capacity of a dealer, fish in excess of the possession limits specified for vessels issued a Federal multispecies permit.

(31) Tamper with, damage, destroy, alter, or in any way distort, render useless, inoperative, ineffective, or inaccurate the VTS, VTS unit, or VTS signal required to be installed on or transmitted by vessel owners or operators required to use a VTS by this part.

(32) Violate any provision of § 651.29.

(33) Land, offload, remove, or otherwise transfer, or attempt to land, offload, remove or otherwise transfer multispecies finfish from one vessel to another vessel, unless both vessels qualify under the exception specified in paragraph (e)(1)(ii) of this section, or unless authorized in writing by the Regional Director pursuant to § 651.30(a).

(34) Assault, resist, oppose, impede, harass, intimidate, or interfere with a NMFS-approved observer aboard a vessel.

(35) Make any false statement, oral or written, to an authorized officer or employee of NMFS, concerning the taking, catching, harvesting, landing, purchase, sale, or transfer of any multispecies finfish.

(36) Make any false statement in connection with an application under § 651.4 or § 651.5 or on any report required to be submitted or maintained under § 651.7.

(37) Interfere with, obstruct, delay, or prevent by any means a lawful investigation or search relating to the enforcement of this part.

(f) In addition to the general prohibitions specified in § 620.7 of this chapter and the prohibitions specified in paragraphs (a) through (e) of this section, it is unlawful for the owner or operator of a charter or party boat issued a permit under § 651.4, or of a recreational vessel, as applicable, to:

(1) Fish with gear in violation of the restrictions specified in § 651.34(a).

(2) Possess regulated species smaller than the minimum sizes specified in § 651.34(b).

(3) Possess cod and haddock in excess of the possession limits specified in § 651.34(c).

(4) Sell, trade, barter, or otherwise transfer, or attempt to sell, trade, barter or otherwise transfer, multispecies finfish for a commercial purpose as specified in § 651.34(d).

(g) It is unlawful to violate any other provision of this part, the Magnuson Act, or any regulation or permit issued under the Magnuson Act.

(h) *Presumption.* The possession for sale of regulated species that do not meet the minimum sizes specified in § 651.23 will be prima facie evidence that such regulated species were taken or imported in violation of these regulations. Evidence that such fish were harvested by a vessel not issued a permit under this part and fishing exclusively within state waters will be sufficient to rebut the presumption. This presumption does not apply to fish being sorted on deck.

5. In § 651.20, paragraph (a)(9) is added and paragraphs (a)(2), (a)(3)(i)(B), (a)(4)(i)(E), (a)(6)(iii)(C), (a)(7), the introductory text of paragraph (a)(8) preceding the tables, paragraphs (a)(8)(i), (a)(8)(iii)(B), (c)(1), (c)(2), (c)(3)(ii), (c)(5), (d), (e)(2), (f)(2), (i), (j) introductory text and (j)(7) are revised to read as follows:

**§ 651.20 Regulated mesh areas and restrictions on gear and methods of fishing.**

\* \* \* \* \*

(a) \* \* \*

(2) *Gear restrictions.* (i) Except as provided in paragraphs (a)(2)(iii) and (j) of this section, and unless otherwise restricted under paragraphs (a)(2)(ii) and (a)(5) of this section, the minimum mesh size for any trawl net, sink gillnet, Scottish seine, mid-water trawl, or purse seine, on a vessel, or used by a vessel fishing under a DAS in the multispecies DAS program in the GOM/GB regulated mesh area, shall be 6 inches (15.24 cm) square or diamond mesh throughout the entire net. This restriction does not apply to nets or pieces of nets smaller than 3 ft (0.9 m) x 3 ft (0.9 m), (9 sq. ft (0.81 m<sup>2</sup>)), or to vessels that have not been issued a Federal multispecies permit under § 651.4 and that are fishing exclusively in state waters.

(ii) *Large Mesh vessels.* When fishing in the GOM/GB regulated mesh area, the minimum mesh size for any sink gillnet on a vessel, or used by a vessel, fishing under a DAS in the Large Mesh DAS program specified in § 651.22(b)(6) shall be 7-inch (17.78-cm) diamond mesh throughout the entire net. The minimum

mesh size for any trawl net on a vessel, or used by a vessel, fishing under a DAS in the Large Mesh DAS program shall be 8-inch (20.32-cm) diamond mesh throughout the entire net. This restriction does not apply to nets or pieces of nets smaller than 3 ft (0.9 m) x 3 ft (0.9 m), (9 sq. ft (0.81 m)), or to vessels that have not been issued a Federal multispecies permit under § 651.4 and that are fishing exclusively in state waters.

(iii) *Other gear and mesh exemptions.* The minimum mesh size for any trawl net, sink gillnet, Scottish seine, mid-water trawl, or purse seine, on a vessel, or used by a vessel, when not fishing under the multispecies DAS program and when fishing in the GOM/GB regulated mesh area, is provided for under the exemptions specified in paragraphs (a)(3), (a)(4), (a)(6), (a)(8), (a)(9), (e), (f), (i), and (j) of this section. Vessels that are not fishing in one of these exemption programs, with exempted gear (as defined under this part), or under the Scallop state waters exemption program specified in § 650.27 of this chapter, or under a multispecies DAS are prohibited from fishing in the GOM/GB regulated mesh area.

(3) \* \* \*

(i) \* \* \*

(B) The following may be retained, with the restrictions noted, as allowable bycatch species in the northern shrimp fishery as described in this section: Longhorn sculpin; up to two standard totes of silver hake (whiting); monkfish and monkfish parts up to 10 percent by weight of all other species on board; and American lobster up to 10 percent by weight of all other species on board or two hundred lobsters, whichever is less.

\* \* \* \* \*

(4) \* \* \*

(i) \* \* \*

(E) The following may be retained, with the restrictions noted, as allowable bycatch species in the Cultivator Shoal whiting fishery exemption area as described in this section: longhorn sculpin; monkfish and monkfish parts up to 10 percent by weight of all other species on board; and American lobster up to 10 percent by weight of all other species on board or two hundred lobsters, whichever is less.

\* \* \* \* \*

(6) \* \* \*

(iii) \* \* \*

(C) Vessels may not fish for, possess on board, or land any species of fish except when fishing in the areas specified in paragraphs (a)(4), (a)(9), (c) and (d) of this section. Vessels may retain exempted small mesh species as

provided in paragraphs (a)(4)(i), (a)(9)(i), (c)(3) and (d)(3), of this section.

(7) *Addition or deletion of exemptions.* (i) An exemption may be added in an existing fishery for which there is sufficient data or information to ascertain the amount of regulated species bycatch, if the Regional Director, after consultation with the Council, determines that the percentage of regulated species caught as bycatch is, or can be reduced to, less than 5 percent by weight of total catch and that such exemption will not jeopardize fishing mortality objectives. In determining whether exempting a fishery may jeopardize meeting fishing mortality objectives, the Regional Director may take into consideration factors such as, but not limited to, juvenile mortality. A fishery can be defined, restricted or allowed by area, gear, season, or other means determined to be appropriate to reduce bycatch of regulated species. An existing exemption may be deleted or modified if the Regional Director determines that the catch of regulated species is equal to or greater than 5 percent by weight of total catch, or that continuing the exemption may jeopardize meeting fishing mortality objectives. Notification of additions, deletions or modifications will be made through publication of a rule in the Federal Register.

(ii) The Council may recommend to the Regional Director, through the framework procedure specified in § 651.40(b), additions or deletions to exemptions for fisheries either existing or proposed for which there may be insufficient data or information for the Regional Director to determine, without public comment, percentage catch of regulated species.

(iii) The Regional Director may, using the process described in either paragraphs (a)(7) (i) or (ii) of this section, authorize an exemption for a white hake fishery by vessels using regulated mesh or hook gear. Determination of the percentage of regulated species caught in such fishery shall not include white hake.

(iv) *Restrictions on exempted fisheries.* Exempted fisheries authorized under this paragraph are subject, at minimum, to the following restrictions:

(A) With the exception of fisheries authorized under paragraph (a)(7)(iii) of this section, possession of regulated species will be prohibited.

(B) Possession of monkfish or monkfish parts will be limited to 10 percent by weight of all other species on board.

(C) Possession of lobsters will be limited to 10 percent by weight of all

other species on board or 200 lobsters, whichever is less.

(D) Possession of skate or skate parts in the SNE regulated mesh area will be limited to 10 percent by weight of all other species on board.

(8) *Small Mesh Area 1/Small Mesh Area 2.* Fisheries using nets of mesh smaller than the minimum size specified in paragraph (a)(2) of this section in subareas described as Small Mesh Area 1 and Small Mesh Area 2 of the Small Mesh Exemption Area as specified under paragraph (a)(3) of this section, and defined in this paragraph (a)(8), have been found to meet the exemption qualification requirements specified in paragraph (a)(7) of this section. Therefore, vessels subject to the mesh restrictions specified in paragraph (a)(2) of this section may fish with or possess nets of mesh smaller than the minimum size specified in paragraph (a)(2) of this section in these areas, if the vessel complies with the restrictions specified in paragraphs (a)(8)(i) through (iii) of this section. These subareas are defined by straight lines connecting the following points in the order stated (see Figure 4 to part 651):

\* \* \* \* \*

(i) The fishing season is from July 15 through October 31 when fishing under the exemption in Small Mesh Area 1.

\* \* \* \* \*

(iii) \* \* \*

(B) *Allowable bycatch.* Vessels fishing for the exempted species identified in paragraph (a)(8)(iii)(A) of this section may also possess and land the following species, with the restrictions noted, as allowable bycatch species: Longhorn sculpin; monkfish and monkfish parts up to 10 percent by weight of all other species on board; and American lobster up to 10 percent by weight of all other species on board or two hundred lobsters, whichever is less.

(9) *Nantucket Shoals dogfish fishery exemption area.* The Nantucket Shoals dogfish fishery as defined in this part has been found to meet the exemption qualification requirements specified in paragraph (a)(7) of this section. Therefore, vessels subject to the mesh restrictions specified in paragraph (a)(2) of this section may fish with, use, or possess nets of mesh smaller than the minimum size specified in paragraph (a)(2) of this section in the Nantucket Shoals dogfish fishery exemption area, if the vessel complies with the requirements specified in paragraph (a)(9)(i) of this section. The Nantucket Shoals dogfish fishery exemption area is defined by straight lines connecting the following points in the order stated (see Figure 4 to part 651):

### NANTUCKET SHOALS DOGFISH EXEMPTION AREA

Point	Latitude	Longitude
NS1 .....	41°45' N	70°00' W.
NS2 .....	41°45' N	69°20' W.
NS3 .....	41°30' N	69°20' W.
CI1 .....	41°30' N	69°23' W.
NS5 .....	41°26.5' N	69°20' W.
NS6 .....	40°50' W	69°20' N.
NS7 .....	40°50' W	70°00' N.
NS1 .....	41°45' N	70°00' W.

(i) *Requirements.* Vessels authorized to fish in this fishery must have on board an authorizing letter issued by the Regional Director. Vessels are subject to the following conditions:

(A) Authorized vessels may not fish for, possess on board or land any species of fish other than dogfish except as provided under paragraph (a)(9)(i)(D) of this section.

(B) Authorized vessels may fish under this exemption during the season of June 1 through October 15.

(C) When transiting the GOM/GB regulated mesh area as specified under paragraph (a)(1) of this section, any nets of mesh smaller than the regulated mesh size specified in paragraph (a)(2) of this section, must be stowed according to the provisions of paragraph (c)(4) of this section.

(D) The following may be retained, with the restrictions noted, as allowable bycatch species in the Nantucket Shoals dogfish fishery exemption area as described in this section: Longhorn sculpin, up to two standard totes of silver hake (whiting); monkfish and monkfish parts up to 10 percent by weight of all other species on board; American lobster up to 10 percent by weight of all other species on board or two hundred lobsters, whichever is less; and skate or skate parts up to 10 percent by weight of all other species on board.

(E) Authorized vessels must comply with any additional gear restrictions specified in the authorization letter issued by the Regional Director.

(ii) *Sea Sampling.* The Regional Director may conduct periodic sea sampling to determine if there is a need to change the area or season designation, and to evaluate the bycatch of regulated species.

\* \* \* \* \*

(c) *Southern New England regulated mesh area.* (1) *Area definition.* The Southern New England regulated mesh area is that area bounded on the east by straight lines connecting the following points in the order stated (see Figure 1 part 651):

### SOUTHERN NEW ENGLAND REGULATED MESH AREA

Point	Latitude	Longitude
G5 .....	41°18.6' N	66°24.8' W.
G6 .....	40°55.5' N	66°38' W.
G7 .....	40°45.5' N	68°00' W.
G8 .....	40°37' N	68°00' W.
G9 .....	40°30.5' N	69°00' W.
NL3 .....	40°22.7' N	69°00' W.
NL2 .....	40°18.7' N	69°40' W.
NL1 .....	40°50' N	69°40' W.
G11 .....	40°50' N	70°00' W.
G12 .....		70°00' W. <sup>1</sup>

<sup>1</sup> Northward to its intersection with the shoreline of mainland Massachusetts; and on the west by the eastern boundary of the Mid-Atlantic regulated mesh area.

(2) *Gear restrictions.* (i) Except as provided in paragraphs (c)(2)(iii) and (j) of this section, and unless otherwise restricted under paragraph (c)(2)(ii) of this section, the minimum mesh size for any trawl net, sink gillnet, Scottish seine, purse seine or mid-water trawl, in use, or available for immediate use as described under paragraph (c)(4) of this section, by a vessel fishing under a DAS in the multispecies DAS program in the Southern New England (SNE) regulated mesh area, shall be 6 inches (15.24 cm) square or diamond mesh throughout the entire net. This restriction does not apply to vessels that have not been issued a Federal multispecies permit under § 651.4 and that are fishing exclusively in state waters.

(ii) *Large Mesh vessels.* When fishing in the SNE regulated mesh area, the minimum mesh size for any sink gillnet on a vessel, or used by a vessel, fishing under a DAS in the Large Mesh DAS program specified in § 651.22(b)(6) shall be 7-inch (17.78-cm) diamond mesh throughout the entire net. The minimum mesh size for any trawl net on a vessel, or used by a vessel, fishing under a DAS in the Large Mesh DAS program shall be 8-inch (20.32-cm) diamond mesh throughout the entire net. This restriction does not apply to nets or pieces of nets smaller than 3 ft (0.9 m)×3 ft (0.9 m), (9 sq. ft (0.81 m<sup>2</sup>)), or to vessels that have not been issued a Federal multispecies permit under § 651.4 and that are fishing exclusively in state waters.

(iii) *Other gear and mesh exemptions.* The minimum mesh size for any trawl net, sink gillnet, Scottish seine, mid-water trawl, or purse seine, in use, or available for immediate use as described under paragraph (c)(4) of this section, by a vessel when not fishing under the multispecies DAS program and when fishing in the SNE regulated mesh area, is provided for under the exemptions specified in paragraphs (c)(3), (e), (f), (i),

and (j) of this section. Vessels that are not fishing in one of these exemption programs, with exempted gear (as defined under this part), or under the Scallop state waters exemption program specified in § 650.27 of this chapter, or under a multispecies DAS are prohibited from fishing in the SNE regulated mesh area.

(3) \* \* \*

(ii) *Possession and net stowage requirements.* Vessels may possess regulated species while in possession of nets with mesh smaller than the minimum size specified in paragraph (c)(2)(i) of this section, provided that the nets are stowed and are not available for immediate use in accordance with paragraph (c)(4) of this section, and provided that regulated species were not harvested by nets of mesh size smaller than the minimum mesh size specified in paragraph (c)(2)(i) of this section. Vessels fishing for the exempted species identified in paragraph (c)(3)(i) of this section may also possess and retain the following species, with the restrictions noted, as incidental take to these exempted fisheries: Conger eels; searobins; black sea bass; red hake; tautog (blackfish); blowfish (puffer); cunner; John Dory; mullet; bluefish; tilefish; longhorn sculpin; fourspot flounder; alewife; hickory shad; American shad; blueback herring; sea ravens; Atlantic croaker; spot; swordfish; monkfish and monkfish parts up to 10 percent by weight of all other species on board; American lobster up to 10 percent by weight of all other species on board or two hundred lobsters, whichever is less; and skate and skate parts up to 10 percent by weight of all other species on board.

\* \* \* \* \*

(5) *Addition or deletion of exemptions.* An exemption may be added, deleted or modified pursuant to the procedure described in paragraph (a)(7) of this section.

(d) *Mid-Atlantic regulated mesh area.*

(1) *Area definition.* The Mid-Atlantic (MA) regulated mesh area is that area bounded on the east by a line running from the Rhode Island shoreline along 71°47.5' W. long. to its intersection with the 3 nautical mile line, south along the 3 nautical mile line to Montauk Point, southwesterly along the 3 nautical mile line to the intersection of 72°30' W. long., and south along that line to the intersection of the outer boundary of the EEZ (see Figure 1 to part 651).

(2) *Gear restrictions.* (i) Except as provided in paragraphs (d)(3) and (j) of this section, and unless otherwise restricted under paragraph (d)(2)(ii) of this section, the minimum mesh size for

any trawl net, sink gillnet, Scottish seine, purse seine or mid-water trawl, in use, or available for immediate use as described under paragraph (c)(4) of this section, by a vessel fishing under a DAS in the multispecies DAS program in the MA regulated mesh area shall be that specified in the summer flounder regulations at § 625.24(a) of this chapter. This restriction does not apply to vessels that have not been issued a Federal multispecies permit under § 651.4 and that are fishing exclusively in state waters.

(ii) *Large mesh vessels.* When fishing in the MA regulated mesh area, the minimum mesh size for any sink gillnet on a vessel, or used by a vessel, fishing under a DAS in the Large Mesh DAS program specified in § 651.22(b)(6) shall be 7-inch (17.78-cm) diamond mesh throughout the entire net. The minimum mesh size for any trawl net on a vessel, or used by a vessel, fishing under a DAS in the Large Mesh DAS program shall be 8-inch (20.32-cm) diamond mesh throughout the net. This restriction does not apply to nets or pieces of nets smaller than 3 ft (0.9 m)×3 ft (0.9 m), (9 sq. ft (0.81 m<sup>2</sup>)), or to vessels that have not been issued a Federal multispecies permit under § 651.4 and that are fishing exclusively in state waters.

(3) *Exemptions.* Vessels in the MA regulated mesh area may fish with or possess nets of mesh size smaller than the minimum size specified in paragraph (d)(2) of this section provided that they do not possess or land multispecies finfish, except as provided in § 651.27(b).

(ii) *Net stowage exemption.* Vessels may possess regulated species while in possession of nets with mesh smaller than the minimum size specified in paragraph (d)(2)(i) of this section, provided that the nets are stowed and are not available for immediate use in accordance with paragraph (c)(4) of this section, and provided that regulated species were not harvested by nets of mesh size smaller than the minimum mesh size specified in paragraph (d)(2)(i) of this section.

(4) *Additional exemptions.* The Regional Director may, using the process described in either (a)(7)(i) or (a)(7)(ii), authorize an exemption for a white hake fishery by vessels using regulated mesh or hook gear. Determination of the percentage of regulated species caught in such a fishery shall not include white hake.

(e) \* \* \*

(2) When fishing under this exemption in the GOM/GB Regulated Mesh Area vessels must have on board

an authorizing letter issued by the Regional Director;

\* \* \* \* \*

(f) \* \* \*

(2) When fishing under this exemption in the GOM/GB Regulated Mesh Area vessels must have on board an authorizing letter issued by the Regional Director;

\* \* \* \* \*

(i) *Scallop vessels.* (1) Except as provided in paragraph (i)(2) of this section, scallop vessels that possess a limited access permit under § 650.4 of this chapter, and that are fishing under the scallop DAS program described in § 650.24, may possess and land up to 300 lb (136.1 kg) of regulated species, unless otherwise restricted pursuant to § 651.27(a)(2).

(2) Combination vessels fishing under a multispecies DAS are subject to the gear restrictions specified in § 651.20 and may possess and land unlimited amounts of regulated species. Such vessels may simultaneously fish under a scallop DAS.

(j) *State waters winter flounder exemption.* Any vessel issued a Federal limited access multispecies permit under this part may fish for, possess, or land winter flounder while fishing with nets of mesh smaller than the minimum size specified in paragraphs (a)(2), (c)(2), and (d)(2) of this section provided that:

\* \* \* \* \*

(7) The vessel, when not fishing under the DAS program, does not fish for, possess, or land more than 500 lb (226.8 kg) of winter flounder;

\* \* \* \* \*

6. In § 651.21, paragraphs (a)(2)(i), (b)(2)(i), (c)(2)(i), (d) and (e) introductory text are revised, and paragraphs (f), (g), and (h) are added to read as follows:

#### § 651.21 Closed areas.

(a) \* \* \*

(2) \* \* \*

(i) Fishing with or using pot gear designed and used to take lobsters, or pot gear designed and used to take hagfish, and that have no other gear on board capable of catching multispecies finfish; and

\* \* \* \* \*

(b) \* \* \*

(2) \* \* \*

(i) Fishing with or using pot gear designed and used to take lobsters, or pot gear designed and used to take hagfish, and that have no other gear on board capable of catching multispecies finfish;

\* \* \* \* \*

(c) \* \* \*

(2) \* \* \*

(i) Fishing with or using pot gear designed and used to take lobsters, or pot gear designed and used to take hagfish, and that have no other gear on board capable of catching multispecies finfish;

\* \* \* \* \*

(d) *Transiting.* Vessels may transit Closed Area I, the Nantucket Lightship Closed Area, the Northeast Closure Area, the Mid-coast Closure Area, and the Massachusetts Bay Closure Area, as defined in paragraphs (a)(1), (c)(1), (f)(1), (g)(1) and (h)(1), respectively, of this section, provided that their gear is stowed in accordance with the provisions of paragraph (e) of this section.

(e) *Gear stowage requirements.* Vessels transiting the closed areas must stow their gear as follows:

\* \* \* \* \*

(f) *Northeast Closure Area.* (1) During the period August 15 through September 13, no fishing vessel or person on a fishing vessel may enter, fish, or be, and no fishing gear capable of catching multispecies finfish, unless otherwise allowed in this part may be, in the area known as the Northeast Closure Area (Figure 3 to part 651), as defined by straight lines connecting the following points in the order stated, except as specified in paragraphs (d) and (f)(2) of this section:

Point	Latitude	Longitude
NE1 .....	Maine shoreline	68°55.0' W.
NE2 .....	43°29.6' N	68°55.0' W.
NE3 .....	44°04.4' N	67°48.7' W.
NE4 .....	44°06.9' N	67°52.8' W.
NE5 .....	44°31.2' N	67°02.7' W.
NE6 .....	Maine shoreline	67°02.7' W.

(2) *Exceptions.* Paragraph (f)(1) of this section does not apply to persons on fishing vessels or fishing vessels:

(i) That have not been issued a Federal multispecies permit under § 651.4 and that are fishing exclusively in state waters;

(ii) Fishing with or using exempted gear as defined under this part, excluding mid-water trawl gear, provided that there is no other gear on board capable of catching multispecies finfish; and

(iii) Classified as charter, party, or recreational.

(g) *Mid-coast Closure Area.* (1) During the period November 1 through December 31, no fishing vessel or person on a fishing vessel may enter, fish, or be, and no fishing gear capable of catching multispecies finfish unless otherwise allowed in this part may be,



in the area known as the Mid-coast Closure Area (Figure 3 to part 651), as defined by straight lines connecting the following points in the order stated, except as specified in paragraphs (d) and (g)(2) of this section:

Point	Latitude	Longitude
MC1 .....	42°30'N	Massachusetts shoreline.
MC2 .....	42°30'N	70°15'W.
MC3 .....	42°40'N	70°15'W.
MC4 .....	42°40'N	70°00'W.
MC5 .....	43°00'N	70°00'W.
MC6 .....	43°00'N	69°30'W.
MC7 .....	43°15'N	69°30'W.
MC8 .....	43°15'N	69°00'W.
MC9 .....	Maine shoreline	69°00'W.

(2) *Exceptions.* Paragraph (g)(1) of this section does not apply to persons on fishing vessels or fishing vessels:

(i) That have not been issued a Federal multispecies permit under § 651.4 and that are fishing exclusively in state waters;

(ii) Fishing with or using exempted gear as defined under this part, excluding mid-water trawl gear, provided that there is no other gear on board capable of catching multispecies finfish; and

(iii) Classified as charter, party, or recreational.

(h) *Massachusetts Bay Closure Area.* (1) During the period March 1 through March 30, no fishing vessel or person on a fishing vessel may enter, fish, or be, and no fishing gear capable of catching multispecies finfish, unless otherwise allowed in this part may be, in the area known as the Massachusetts Bay Closure Area (Figure 3 to part 651), as defined by straight lines connecting the following points in the order stated, except as specified in paragraphs (d) and (h)(2) of this section:

Point	Latitude	Longitude
MB1 .....	42°30' N	Massachusetts shoreline.
MB2 .....	42°30' N	70°30' W.
MB3 .....	42°12' N	70°30' W.
MB4 .....	42°12' N	70°00' W.
MB5 .....	Cape Cod shoreline	70°00' W.
MB6 .....	42°00' N	Cape Cod shoreline.
MB7 .....	42°00' N	Massachusetts shoreline.

(2) *Exceptions.* Paragraph (h)(1) of this section does not apply to persons on fishing vessels or fishing vessels:

(i) That have not been issued a Federal multispecies permit under § 651.4 and that are fishing exclusively in state waters;

(ii) Fishing with or using exempted gear as defined under this part, excluding mid-water trawl gear, provided that there is no other gear on board capable of catching multispecies finfish; and

(iii) Classified as charter, party, or recreational.

7. Section 651.22 is revised to read as follows:

**§ 651.22 Effort-control program for limited access vessels.**

(a) A limited access multispecies vessel issued a permit under § 651.4(b) may not fish for, possess or land regulated species except during a DAS as allocated under and in accordance with the applicable DAS program described below, unless otherwise provided in these regulations.

(b) *DAS program—Permit categories, allocations and initial assignments to categories.* Beginning with the 1996 fishing year, all limited access multispecies permit holders shall be assigned to one of the following DAS permit categories according to the criteria specified. Permit holders may request a change in permit category for the 1996 fishing year and all fishing years thereafter as specified in § 651.4(f)(3). Each fishing year shall begin on May 1 and extend through April 30 of the following year.

(1) *Individual DAS Category—(i) DAS allocation.* Vessels fishing under the Individual DAS category shall be allocated 65 percent of their initial 1994 allocation baseline as established under Amendment 5 to the FMP for the 1996 fishing year and 50 percent of the vessel's initial allocation baseline for the 1997 fishing year and beyond, as calculated under paragraph (d)(1) of this section.

(ii) *Initial assignment.* All vessels issued valid Individual DAS limited access multispecies permits, including vessels also issued limited access multispecies Gillnet category permits, as of the effective date of the final rule for Amendment 7, shall be initially assigned to this category.

(2) *Fleet DAS Category—(i) DAS allocation.* Vessels fishing under the Fleet DAS category shall be allocated 139 DAS for the 1996 fishing year, and 88 DAS for the 1997 fishing year and beyond.

(ii) *Initial assignment.* As of the effective date of the final rule for Amendment 7, vessels issued valid permits in one of the following categories shall be initially assigned to this category: Fleet DAS permit holders, including vessels also issued limited access multispecies Gillnet category permits; limited access multispecies

Hook-Gear permit holders; limited access multispecies Gillnet permit holders that have not also been issued a permit in a DAS permit category; limited access multispecies  $\leq 45$  ft (13.7 m) category permit holders that are larger than 20 ft (6.1 m) in length as determined by the most recent permit application.

(3) *Small vessel category—(i) DAS allocation.* Vessels qualified and electing to fish under the Small Vessel category may retain cod, haddock, and yellowtail flounder, combined up to 300 lb (136.1 kg) per trip without being subject to DAS restrictions. These vessels are not subject to a possession limit for the other multispecies finfish.

(ii) *Initial assignment.* All vessels issued a valid limited access multispecies permit and fishing under the Small boat exemption (less than or equal to 45 ft (13.7 m)) permit as of the effective date of the final rule for Amendment 7, and that are 20 ft (6.1 m) or less in length as determined by the vessel's last application for a permit shall be initially assigned to this category. Other vessels may elect to change into this category as provided for in § 651.4(f)(3) if such vessel meets or complies with the following:

(A) The vessel is 30 ft (9.1 m) or less in length overall as determined by measuring along a horizontal line drawn from a perpendicular raised from the outside of the most forward portion of the stem of the vessel to a perpendicular raised from the after most portion of the stern;

(B) Vessels for which construction was begun after May 1, 1994, must be constructed such that the quotient of the overall length divided by the beam will not be less than 2.5; and

(C) Acceptable verification for vessels 20 ft (6.1 m) or less in length shall be U.S. Guard documentation or state registration papers. For vessels over 20 ft (6.1 m) in length, the measurement of length must be verified in writing by a qualified marine surveyor, or the builder, based on the boat's construction plans, or by other means determined acceptable by the Regional Director. A copy of the verification must accompany an application for a Federal multispecies permit issued under § 651.4.

(D) Adjustments to the small-boat category requirements, including changes to the length requirement, if required to meet fishing mortality goals, may be made following a reappraisal and analysis under the framework provisions specified in subpart C of this part.

(4) *Hook-Gear Category—(i) DAS allocation.* Vessels issued a valid



limited access multispecies Hook-Gear permit shall be allocated 139 DAS for the 1996 fishing year and 88 DAS for the 1997 fishing year and beyond. A vessel fishing in this permit category under the DAS program must meet or comply with the following while fishing for, in possession of, or landing, regulated species:

(A) Vessels, and persons on such vessels, are prohibited from possessing gear other than hook gear on board the vessel; and

(B) Vessels, and persons on such vessels, are prohibited from fishing, setting, or hauling back, per day, or possessing on board the vessel, more than 4,500 rigged hooks. An unbaited hook and gangion that has not been secured to the ground line of the trawl on board a vessel is deemed to be a replacement hook and is not counted toward the 4,500 hook limit. A "snap-on" hook is deemed to be a replacement hook if it is not rigged or baited.

(ii) *Initial assignment.* No vessel shall be initially assigned to the Hook-Gear category. Any vessel that meets the qualifications specified in § 651.4(b)(1) may apply for and obtain a permit to fish under this category.

(5) *Combination Vessel Category—(i) DAS allocation.* Vessels fishing under the Combination Vessel category shall be allocated 65 percent of their initial 1994 allocation baseline as established under Amendment 5 to the FMP for the 1996 fishing year and 50 percent of the vessel's initial allocation baseline for the 1997 fishing year and beyond, as calculated under paragraph (d)(1) of this section.

(ii) *Initial assignment.* All vessels issued a valid limited access multispecies permit qualified to fish as a Combination Vessel as of the effective date of the final rule for Amendment 7 shall be assigned to this category.

(6) *Large Mesh DAS Category—(i) DAS allocation.* Vessels fishing under the Large Mesh DAS category shall be allocated 155 DAS for the 1996 fishing year, and 120 DAS for the 1997 fishing year and beyond. To be eligible to fish under the Large Mesh DAS permit category a vessel must fish with gillnet gear with a minimum mesh net of 7-inch (17.78-cm) diamond or trawl gear with a minimum mesh size of 8-inch (20.32-cm) diamond, as described under § 651.20(a)(2)(ii), (c)(2)(ii), and (d)(2)(ii).

(ii) *Initial assignment.* No vessel shall be initially assigned to the Large Mesh DAS category. Any vessel that is initially assigned to the Individual DAS, Fleet DAS, or Small Vessel permit category may request and be granted a change in category into this category as specified in § 651.4(f)(3).

(c) *1996 DAS appeals.* A vessel that was issued a valid 1995 limited access multispecies permit and fishing under the Small boat exemption (less than or equal to 45 ft (13.7 m)), Hook-Gear or Gillnet permit categories, that elects to fish under the Individual DAS category, and has not previously been allocated Individual DAS, is eligible to appeal its allocation of DAS if it has not previously done so, as described under paragraph (d)(2) of this section. Each of these vessel's initial allocation of Individual DAS will be considered to be 176 for purposes of this appeal (that is, the Fleet DAS category baseline prior to the 1996–1997 reductions).

(d) *Individual DAS allocations—(1) Calculation of a vessel's Individual DAS.* The DAS assigned to a vessel for purposes of determining that vessel's annual allocation under the Individual DAS Program shall be calculated as follows:

(i) Calculate the total number of the vessel's multispecies DAS for the years 1988, 1989, and 1990. Multispecies DAS are deemed to be the total number of days the vessel was absent from port for a trip where greater than 10 percent of the vessel's total landings were comprised of regulated species, minus any days for such trips in which a scallop dredge was used;

(ii) Exclude the year of least multispecies DAS; and

(iii) If 2 years of multispecies DAS are remaining, average those years' DAS, or, if only 1 year remains, use that year's DAS.

(2) *Appeal of DAS allocation—(i) Appeal criteria.* Initial allocations of Individual DAS to those vessels authorized to appeal under paragraph (c) of this section may be appealed to the Regional Director if a request to appeal is received by the Regional Director no later than July 31, 1996, or 30 days after the initial allocation is made, whichever is later. Any such appeal must be in writing and be based on one or more of the following grounds:

(A) The information used by the Regional Director was based on mistaken or incorrect data;

(B) The applicant was prevented by circumstances beyond his/her control from meeting relevant criteria; or

(C) The applicant has new or additional information.

(ii) The Regional Director will appoint a designee who will make an initial decision on the written appeal.

(iii) If the applicant is not satisfied with the initial decision, the applicant may request that the appeal be presented at a hearing before an officer appointed by the Regional Director.

(iv) The hearing officer shall present his/her findings to the Regional Director and the Regional Director will make a decision on the appeal. The Regional Director's decision on this appeal is the final administrative decision of the Department of Commerce.

(3) *Status of vessels pending appeal of DAS allocations.* Vessels, while their Individual DAS allocation is under appeal, may fish under the Fleet DAS category until the Regional Director has made a final determination on the appeal. Any DAS spent fishing for regulated species by a vessel while that vessel's initial DAS allocation is under appeal, shall be counted against any DAS allocation that the vessel may ultimately receive.

(e) *Accrual of DAS.* DAS shall accrue in hourly increments, with all partial hours counted as full hours.

(f) *Good Samaritan credit.* Limited access vessels fishing under the DAS program and that spend time at sea for one of the following reasons, and that can document the occurrence through the U.S. Coast Guard, will be credited for the time documented:

(1) Time spent assisting in a U.S. Coast Guard search and rescue operation; or

(2) Time spent assisting the U.S. Coast Guard in towing a disabled vessel.

(g) *Spawning season restrictions.* Vessels issued a valid Small Vessel category permit under paragraph (b)(3) of this section may not fish for, possess, or land regulated species between March 1 and March 20 of each year. All other vessels issued limited access permits must declare out and be out of the regulated multispecies finfish fishery for a 20-day period between March 1 and May 31 of each fishing year using the notification requirements specified under § 651.29. If a vessel owner has not declared, or taken, the period of time required between March 1 and May 31 of each fishing year on or before May 12 of each such year, the vessel is prohibited from fishing for, possessing or landing any regulated species during the period May 12 through May 31, inclusive.

(h) *Declaring DAS and 20-day blocks.* A vessel's owner or authorized representative shall notify the Regional Director of a vessel's participation in the DAS program and declaration of its 20-day spawning period out of the multispecies fishery using the notification requirements specified under § 651.29.

(i) *Adjustments in annual DAS allocations.* Adjustments in annual DAS allocations, if required to meet fishing mortality goals, may be made following

a reappraisal and analysis as specified in subpart C of this part.

8. In § 651.23, the introductory text of paragraph (a) and paragraphs (d) and (e) are revised to read as follows:

**§ 651.23 Minimum fish size.**

(a) Minimum fish sizes for recreational vessels and charter/party vessels that are not fishing under a multispecies DAS are specified in § 651.34. All other vessels are subject to minimum fish sizes (total length) as follows:

\* \* \* \* \*

(d) *Exception.* (1) Each person aboard a vessel issued a limited access permit and fishing under the DAS program may possess up to 25 lb (11.3 kg) of fillets that measure less than the minimum size, if such fillets are from legal-sized fish and are not offered or intended for sale, trade, or barter.

(e) *Adjustments of minimum size.* (1) At anytime when information is available, the Council will review the best available mesh selectivity information to determine the appropriate minimum size for the species listed in paragraph (a) of this section, except winter flounder, according to the length at which 25 percent of the regulated species would be retained by the applicable minimum mesh size.

(2) Upon determination of the appropriate minimum sizes, the Council shall propose the minimum fish sizes to be implemented following the procedures specified in subpart C of this part.

(3) Additional adjustments or changes to the minimum fish sizes specified in paragraphs (a) and (b) of this section, and exemptions as specified in paragraphs (a) and (b) of this section, and exemptions as specified in paragraph (c) of this section, may be made at any time after implementation of the final rule as specified under subpart C of this part.

9. Section 651.27 is revised to read as follows:

**§ 651.27 Additional possession limits on haddock and winter flounder.**

(a) *Haddock*—(1) *Multispecies DAS vessels.* A vessel issued a limited access multispecies permit under this part that is fishing under a multispecies DAS may land, or possess on board, up to 1000 lb (453.6 kg) of haddock. Haddock on board a vessel subject to this possession limit must be separated from other species of fish and stored so as to be readily available for inspection.

(2) *Scallop dredge vessels*—(i) No person owning or operating a scallop dredge vessel issued a permit under this

part may land haddock from, or possess haddock on board, a scallop dredge vessel, from January 1 through June 30.

(ii) No person owning or operating a scallop dredge vessel without a permit under this part may possess haddock in, or harvested from, the EEZ, from January 1 through June 30.

(iii) From July 1 through December 31, no scallop dredge vessel or persons owning or operating a scallop dredge vessel, that is fishing under the scallop DAS program as described in § 651.20(i), may land, or possess on board, more than 300 lbs (136.1 kg) of haddock. Haddock on board a vessel subject to this possession limit must be separated from other species of fish and stored so as to be readily available for inspection.

(b) *Winter flounder.* A vessel issued a limited access permit under this part that is fishing in the MA regulated mesh area and is not fishing under a multispecies DAS, may land, or possess on board, winter flounder up to 10 percent by weight of all other species on board or 200 lb (90.7 kg), whichever is less. Winter flounder on board a vessel subject to this possession limit must be separated from other species of fish and stored so as to be readily available for inspection in standard totes.

(c) Vessels are subject to any other applicable possession limit restrictions of this part.

10. In § 651.28, the heading and the first sentence of paragraph (a), and paragraphs (b) and (c) are revised to read as follows:

**§ 651.28 Monitoring requirements.**

(a) *Individual DAS limited access multispecies vessels.* Unless otherwise authorized or required by the Regional Director under § 651.29(b), vessel owners fishing under the Individual DAS program and Combination Vessels must have installed on board an operational VTS unit that meets the minimum performance criteria specified in paragraph (a)(2) of this section, or as modified annually as specified in paragraph (a)(1) of this section. \* \* \*

(b) *Fleet DAS and other limited access multispecies vessels.* Vessels issued limited access multispecies permits who are participating in a DAS program and who are not required to provide notification using a VTS shall be subject to the call-in requirements specified in § 651.29(b).

(c) *Charter/party vessels.* Charter/party vessels that are not fishing under a multispecies DAS are subject to the following requirements:

(1) A vessel must declare into and out of the charter/party fishery providing notification under § 651.29(b).

(2) Vessels that declare into the charter/party fishery are subject to the restrictions in § 651.34.

(3) Once a vessel has declared into the charter/party fishery, that vessel must remain in the charter/party fishery for a minimum of 24 hours.

11. Section 651.29 is revised to read as follows:

**§ 651.29 DAS notification program.**

(a) *VTS notification.* Unless otherwise authorized by the Regional Director as specified in paragraph (c) of this section, owners of vessels issued limited access multispecies permits that have elected to or are required to use a VTS system shall be subject to the following requirements:

(1) Vessels that are issued limited access multispecies permits, that have crossed the demarcation line specified under paragraph (d)(ii) of this section, are deemed to be fishing under the DAS program unless the vessel's owner or authorized representative declares the vessel out of the multispecies fishery, by notifying the Regional Director through the VTS. The owner or authorized representative of any vessel that has been declared out of the multispecies fishery must notify the Regional Director through the VTS prior to leaving port on the vessel's next trip under the DAS program.

(2) If the VTS is not available, or not functional, and if authorized by the Regional Director, a vessel owner must comply with the call-in notification requirements specified in paragraph (b) of this section.

(3) Notification that the vessel is not under the DAS program must be received prior to the vessel leaving port. A change in status of a vessel cannot be made after the vessel leaves port or before it returns to port on any fishing trip.

(b) *Call-in notification.* Vessel owners authorized or required to provide notification using the call-in system shall be subject to the following requirements:

(1) The vessel owner or authorized representative shall notify the Regional Director, prior to leaving port, that the vessel will be participating in the applicable DAS program, or the charter party fishery, by calling 1-800-260-8204 or 508-281-9335, and providing the following information: Vessel name and permit number, owner and caller name and phone number, the type of trip to be taken, the port of departure, and that the vessel is beginning a trip.

(2) A multispecies DAS, or a vessel's participation in the charter/party fishery, begins once the call has been

received and confirmation given by the Regional Director.

(3) A vessel must keep its confirmation number on board for the duration of the trip and must provide it to an authorized officer upon request.

(4) Upon returning to port, at the conclusion of a trip as defined in paragraph (d) of this section or when the vessel is leaving the charter/party fishery, the vessel owner or owner's representative shall notify the Regional Director that the trip has ended by calling 1-800-260-8204 or 508-281-9335, and providing the following information: Vessel name and permit number, owner and caller name and telephone number, port landed, confirmation number, and that the trip has ended.

(5) A DAS, or the vessel's participation in the charter/party fishery, ends when the call has been received and confirmation given by the Regional Director.

(6) Any vessel issued a limited access multispecies permit subject to the DAS program and call-in requirement, that possess or lands regulated species, except as provided in § 651.23, shall be deemed in the DAS program for purposes of counting DAS, regardless of whether or not the vessel's owner or authorized representative provided adequate notification as required by this part.

(7) Any change in status of a vessel cannot be done after leaving port on any fishing trip.

(c) *Temporary authorization for use of the call-in system.* The Regional Director may authorize or require, on a temporary basis, the use of an alternative call-in system of notification. If the call-in system is authorized or required, the Regional Director shall notify affected permit holders through a letter, notification in the Federal Register, or other appropriate means. Vessel owners authorized or required by the Regional Director to provide

notification by a call-in system under this paragraph shall be subject to the requirements specified in paragraph (b) of this section.

(d) *Counting of DAS.* DAS shall be counted as follows:

(1) *Vessels fishing under the VTS system.* (i) DAS for vessels that are under the VTS monitoring system described in § 651.29(a) are counted beginning with the first hourly location signal received showing that the vessel crossed the Vessel Tracking System Demarcation Line leaving port. A trip concludes and accrual of DAS ends with the first hourly location signal received showing that the vessel crossed the Vessel Tracking System Demarcation Line upon its return to port.

(ii) *Vessel Tracking System Demarcation Line.* The VTS Demarcation Line is defined as straight lines connecting the following points in the order stated (see Figures 6 and 7 to part 651):

#### VESSEL TRACKING SYSTEM DEMARCATION LINE

Description	Longitude	Latitude
1. Northern terminus point (Canada land mass)	45°03' N	66°47' W.
2. A point east of West Quoddy Head Light	44°48.9' N	66°56.1' W.
3. A point east of Little River Light	44°39.0' N	67°10.5' W.
4. Whistle Buoy "8BI" (SSE of Baker Island)	44°13.6' N	68°10.8' W.
5. Isle au Haut Light	44°03.9' N	68°39.1' W.
6. Pemaquid Point Light	43°50.2' N	69°30.4' W.
7. A point west of Halfway Rock	43°38.0' N	70°05.0' W.
8. A point east of Cape Neddick Light	43°09.9' N	70°34.5' W.
9. Merrimack River Entrance "MR" Whistle Buoy	42°48.6' N	70°47.1' W.
10. Halibut Point Gong Buoy "1AHP"	42°42.0' N	70°37.5' W.
11. Connecting reference point	42°40' N	70°30' W.
12. Whistle Buoy "2" off Eastern Point	42°34.3' N	70°39.8' W.
13. The Graves Light (Boston)	42°21.9' N	70°52.2' W.
14. Minots Ledge Light	42°16.2' N	70°45.6' W.
15. Farnham Rock Lighted Bell Buoy	42°05.6' N	70°36.5' W.
16. Cape Cod Canal Bell Buoy "CC"	41°48.9' N	70°27.7' W.
17. A point inside Cape Cod Bay	41°48.9' N	70°05' W.
18. Race Point Lighted Bell Buoy "RP"	42°04.9' N	70°16.8' W.
19. Peaked Hill Bar Whistle Buoy "2PH"	42°07.0' N	70°06.2' W.
20. Connecting point, off Nauset Light	41°50' N.	69°53' W.
21. A point south of Chatham "C" Whistle Buoy	41°38' N.	69°55.2' W.
22. A point in eastern Vineyard Sound	41°30' N.	70°33' W.
23. A point east of Martha's Vineyard	41°22.2' N	70°24.6' W.
24. A point east of Great Pt. Light, Nantucket	41°23.4' N.	69°57' W.
25. A point SE of Sankaty Head, Nantucket	41°13' N	69°57' W.
26. A point west of Nantucket	41°15.6' N	70°25.2' W.
27. Squibnocket Lighted Bell Buoy "1"	41°15.7' N	70°46.3' W.
28. Wilbur Point (on Sconticut Neck)	41°35.2' N	70°51.2' W.
29. Misham Point (on Smith Neck)	41°31.0' N	70°57.2' W.
30. Sakonnet Entrance Lighted Whistle Buoy "SR"	41°25.7' N	71°13.4' W.
31. Point Judith Lighted Whistle Buoy "2"	41°19.3' N	71°28.6' W.
32. A point off Block Island Southeast Light	41°08.2' N	71°32.1' W.
33. Shinnecock Inlet Lighted Whistle Buoy "SH"	40°49.0' N	72°28.6' W.
34. Scotland Horn Buoy "S", off Sandy Hook (NJ)	40°26.5' N	73°55.0' W.
35. Barnegat Lighted Gong Buoy "2"	39°45.5' N	73°59.5' W.
36. A point east of Atlantic City Light	39°21.9' N	74°22.7' W.
37. A point east of Hereford Inlet Light	39°00.4' N	74°46' W.
38. A point east of Cape Henlopen Light	38°47' N	75°04' W.
39. A point east of Fenwick Island Light	38°27.1' N	75°02' W.
40. A point NE of Assateague Island (VA)	38°00' N	75°13' W.
41. Wachapreague Inlet Lighted Whistle Buoy "A"	37°35.0' N.	75°33.7' W.
42. A point NE of Cape Henry	36°55.6' N	75°58.5' W.
43. A point east of Currituck Beach Light	36°22.6' N	75°48' W.

## VESSEL TRACKING SYSTEM DEMARCATION LINE—Continued

Description	Longitude	Latitude
44. Oregon Inlet (NC) Whistle Buoy .....	35°48.5' N	75°30' W.
45. Wimple Shoals, east of Chicamacomico .....	35°36' N	75°26' W.
46. A point SE of Cape Hatteras Light .....	35°12.5' N	75°30' W.
47. Hatteras Inlet Entrance Buoy "HI" .....	35°10' N	75°46' W.
48. Ocracoke Inlet Whistle Buoy "OC" .....	35°01.5' N	76°00.5' W.
49. A point east of Cape Lookout Light .....	34°36.5' N	76°30' W.
50. Southern terminus point .....	34°35' N	76°41' W.

(2) *Gillnet vessels under the call-in system.* Accrual of DAS under the call-in notification system for vessels fishing with gillnet gear begins once the phone call has been received, and confirmation has been given by the Regional Director. DAS continue to accrue as long as the vessel's gillnet gear remains in the water or on the vessel when returning to port. A trip concludes and accrual of DAS ends when a vessel returns to port with all of its gillnet gear that was in the water on board, the phone call has been received, and confirmation has been given by the Regional Director.

(3) *All other vessels under the call-in system.* Accrual of DAS under the call-in notification system begins once the phone call has been received and confirmation has been given by the Regional Director. A trip concludes and accrual of DAS ends when after returning to port, the phone call has been received and confirmation has been given by the Regional Director.

12. In § 651.31, paragraph (d) is added to read as follows:

**§ 651.31 At-sea observer coverage.**

\* \* \* \* \*

(d) *Industry funded observer coverage.* NMFS may accept observer coverage funded by outside sources provided the following requirements are met:

(1) All coverage conducted by such observers is determined by NMFS to be in compliance with NMFS' observer guidelines and procedures;

(2) The owner or operator of the vessel complies with all other provisions of this part; and

(3) The observer is approved by the Regional Director.

13. Section 651.32 is revised to read as follows:

**§ 651.32 Sink gillnet requirements to reduce harbor porpoise takes.**

(a) *Areas closed to sink gillnets.* The closed area restrictions prohibiting sink gillnets in the areas and times specified in § 651.21(f) through § 651.32(h) are implemented in order to reduce the takes of harbor porpoise consistent with the harbor porpoise mortality reduction goals. Additional restrictions may be implemented following a reappraisal

and analysis under the framework provisions specified in paragraph (b) of this section.

(b) *Framework adjustment.* (1) At least annually the Regional Director will provide the Council with the best available information on the status of Gulf of Maine harbor porpoise including estimates of abundance and estimates of bycatch in the sink gillnet fishery. Within 60 days of receipt of that information, the Council's Harbor Porpoise Review Team shall complete a review of the data, assess the adequacy of existing regulations, evaluate the impacts of other measures that reduce harbor porpoise take and, if necessary, recommend additional measures in light of the Council's harbor porpoise mortality reduction goals. In addition, the HPRT shall make a determination on whether other conservation issues exist that require a management response to meet the goals and objectives outlined in the FMP. The HPRT shall report its findings and recommendations to the Council.

(2) After receiving and reviewing the HPRT's findings and recommendations, the Council shall determine whether adjustments or additional management measures are necessary to meet the goals and objectives of the FMP. If the Council determines that adjustments or additional management measures are necessary, or at any other time in consultation with the HPRT, it shall develop and analyze appropriate management actions over the span of at least two Council meetings.

(3) The Council may request at any time that the HPRT review and make recommendations on any harbor porpoise take reduction measures or develop additional take reduction proposals.

(4) The Council shall provide the public with advance notice of the availability of the proposals, appropriate rationale, economic and biological analyses, and opportunity to comment on them prior to and at the second Council meeting. The Council's recommendation on adjustments or additions to management measures must come from one or more of the

categories specified under § 651.40(b)(1).

(5) If the Council recommends that the management measures should be published as a final rule, the Council must consider at least the factors specified in § 651.40(b)(2).

(6) The Regional Director may accept, reject, or with Council approval, modify the Council's recommendation, including the Council's recommendation to publish a final rule, as specified under § 651.40(b)(3).

14. Section 651.33 is revised to read as follows:

**§ 651.33 Open access permit restrictions.**

(a) *Handgear permit.* A vessel issued a valid open access Handgear permit issued under § 651.4(c) is subject to the following restrictions:

(1) The vessel may possess and land up to 300 lb (136.1 kg) of cod, haddock, and yellowtail flounder, combined, per trip, and unlimited amounts of the other multispecies finfish provided that it does not use, or possess on board, gear other than rod and reel or handlines while in possession of, fishing for, or landing multispecies finfish.

(2) A vessel may not fish for, possess, or land regulated species between March 1 and March 20 of each year.

(b) *Charter/party permit.* A vessel that has been issued a valid open access Charter/party permit under § 651.4(c), and has declared into the charter/party fishery, is subject to the restrictions on gear, recreational minimum fish sizes and prohibitions on sale specified in § 651.34, and any other applicable provisions of this part.

(c) *Scallop Multispecies Possession Limit Permit.* A vessel that has been issued a valid open access Scallop Multispecies Possession Limit permit under § 651.4(c) may possess and land up to 300 lb (136.1 kg) of regulated species when fishing under a scallop DAS as described under § 651.20(i), provided the vessel does not fish for, possess or land haddock during January 1 through June 30 as specified under § 651.27(a)(2)(i).

15. Section 651.34 is added to subpart B to read as follows:

**§ 651.34 Recreational and charter/party restrictions.****(a) Recreational gear restrictions.**

Persons aboard charter or party vessels permitted under this part and not fishing under the DAS program, and recreational fishing vessels in the EEZ,

are prohibited from fishing with more than two hooks per line and one line per angler and must stow all other fishing gear on board the vessel as specified under §§ 651.20(c)(4) and 651.21(e)(2), 651.21(e)(3) and 651.21(e)(4).

(b) *Recreational minimum fish sizes.*  
(1) Persons aboard charter or party vessels permitted under this part and not fishing under the DAS program, and recreational fishing vessels in the EEZ, are subject to minimum fish sizes (total length) as follows:

**RECREATIONAL**

Species	Inches	
	1996	1997+
Cod .....	20 (50.8 cm)	21 (53.3 cm).
Haddock .....	20 (50.8 cm)	21 (53.3 cm).
Pollock .....	19 (48.3 cm)	19 (48.3 cm).
Witch flounder (gray sole) .....	14 (35.6 cm)	14 (35.6 cm).
Yellowtail flounder .....	13 (33.0 cm)	13 (33.0 cm).
American plaice (dab) .....	14 (35.6 cm)	14 (35.6 cm).
Winter flounder (blackback) .....	12 (30.5 cm)	12 (30.5 cm).
Redfish .....	9 (22.9 cm)	9 (22.9 cm).

(2) *Exception.* Vessels may possess fillets less than the minimum size specified if the fillets are taken from legal-sized fish and are not offered or intended for sale, trade or barter.

(c) *Possession restrictions.* Each person on a recreational vessel may not possess more than 10 cod and/or haddock, combined, in or harvested from the EEZ:

(1) For purposes of counting fish, fillets will be converted to whole fish at the place of landing by dividing fillet number by two. If fish are filleted into a single (butterfly) fillet, such fillet shall be deemed to be from one whole fish.

(2) Cod and haddock harvested by recreational vessels with more than one person aboard may be pooled in one or more containers. Compliance with the possession limit will be determined by dividing the number of fish on board by the number of persons aboard. If there is a violation of the possession limit on board a vessel carrying more than one person, the violation shall be deemed to have been committed by the owner and operator.

(3) Cod and haddock must be stored, so as to be readily available for inspection.

(d) *Restrictions on sale.* It is unlawful to sell, barter, trade, or otherwise transfer for a commercial purpose, or to attempt to sell, barter, trade, or otherwise transfer for a commercial purpose, multispecies finfish caught or landed by charter or party vessels permitted under this part not fishing under a DAS or a recreational fishing vessels fishing in the EEZ.

15. Section 651.40 is revised to read as follows:

**§ 651.40 Framework Specifications.**

(a) *Annual review.* The Multispecies Monitoring Committee (MSMC) shall meet on or before November 15 of each year to develop target TACs for the upcoming fishing year and options for Council consideration on any changes, adjustment or additions to DAS allocations, closed areas or other measures necessary to achieve the FMP goals and objectives.

(1) The MSMC must review available data pertaining to the following:

- (i) Catch and landings;
- (ii) DAS and other measures of fishing effort;
- (iii) Survey results;
- (iv) Stock status;
- (v) Current estimates of fishing mortality; and
- (vi) Any other relevant information.

(2) Based on this review, the MSMC shall recommend target TACs and develop options necessary to achieve the FMP goals and objectives, which may include a preferred option. The MSMC must demonstrate through analysis and documentation that the options it develops are expected to meet the FMP goals and objectives. The MSMC may review the performance of different user groups or fleet sectors in developing options. The range of options developed by the MSMC may include any of the management measures in the FMP including, but not limited to:

- (i) The annual target TACs which must be based on the projected fishing mortality levels required to meet the goals and objectives outlined in the FMP for the 10 regulated species;
- (ii) DAS changes;
- (iii) Possession limits;
- (iv) Gear restrictions;
- (v) Closed areas;

- (vi) Permitting restrictions;
- (vii) Minimum fish sizes;
- (viii) Recreational fishing measures;

and

(ix) Any other management measures currently included in the FMP.

(3) The Council shall review the recommended target TACs and all of the options developed by the MSMC, other relevant information, consider public comment, and develop a recommendation to meet the FMP objective that is consistent with other applicable law. If the Council does not submit a recommendation that meets the FMP objectives and is consistent with other applicable law, the Regional Director may adopt any option developed by the Council, as specified in (a)(5) of this section, provided that the option meets the FMP objective and is consistent with other applicable law.

(4) Based on this review, the Council shall submit a recommendation to the Regional Director of any changes, adjustments or additions to DAS allocations, closed areas or other measures necessary to achieve the FMP's goals and objectives. Included in the Council's recommendation will be supporting documents, as appropriate, concerning the environmental and economic impacts of the proposed action and the other options considered by the Council.

(5) If the Council submits, on or before January 7, a recommendation to the Regional Director after one Council meeting, and the Regional Director concurs with the recommendation, the Regional Director shall publish the Council's recommendation in the Federal Register as a proposed rule. The Federal Register notification of proposed action will provide for a 30-

day public comment period. The Council may instead submit its recommendation on or before February 1 if it chooses to follow the framework process outlined in paragraph (b) of this section and requests that the Regional Director publish the recommendation as a final rule. If the Regional Director concurs that the Council's recommendation meets the FMP objective and is consistent with other applicable law and determines that the recommended management measures be published as a final rule, the action will be published as a final rule in the Federal Register. If the Regional Director concurs that the recommendation meets the FMP objective and is consistent with other applicable law and determines that a proposed rule is warranted, and as a result the effective date of a final rule falls after the start of the fishing year on May 1, fishing may continue. However, DAS used by a vessel on or after May 1 will be counted against any DAS allocation the vessel ultimately receives for that year.

(6) If the Regional Director concurs in the Council's recommendation, a final rule shall be published in the Federal Register on or about April 1 of each year, with the exception noted in paragraph (a)(5) of this section. If the Council fails to submit a recommendation to the Regional Director by February 1 that meets the FMP goals and objectives, the Regional Director may publish as a proposed rule one of the options reviewed and not rejected by the Council, provided that the option meets the FMP objective and is consistent with other applicable law. If, after considering public comment, the Regional Director decides to approve the option published as a proposed rule, the action will be published as a final rule in the Federal Register.

(b) *Within season management action.* The Council may, at any time, initiate action to add or adjust management measures if it finds that action is necessary to meet or be consistent with the goals and objectives of the FMP.

(1) *Adjustment process.* After a management action has been initiated,

the Council shall develop and analyze appropriate management actions over the span of at least two Council meetings. The Council shall provide the public with advance notice of the availability of both the proposals and the analysis, and opportunity to comment on them prior to and at the second Council meeting. The Council's recommendation on adjustments or additions to management measures must come from one or more of the following categories:

- (i) DAS changes;
- (ii) Effort monitoring;
- (iii) Data reporting;
- (iv) Possession limits;
- (v) Gear restrictions;
- (vi) Closed areas;
- (vii) Permitting restrictions;
- (viii) Crew limits;
- (ix) Minimum fish sizes;
- (x) Onboard observers;
- (xi) Minimum hook size and hook style;
- (xii) The use of crucifiers in the hook fishery;
- (xiii) Fleet sector shares;
- (xiv) Recreational fishing measures;
- (xv) Area closures and other appropriate measures to mitigate marine mammal entanglements and interactions; and
- (xvi) Any other management measures currently included in the FMP.

(2) *Council recommendation.* After developing management actions and receiving public testimony, the Council shall make a recommendation to the Regional Director. The Council's recommendation must include supporting rationale, and, if management measures are recommended, an analysis of impacts, and a recommendation to the Regional Director on whether to publish the management measures as a final rule. If the Council recommends that the management measures should be published as a final rule, the Council must consider at least the following factors and provide support and analysis for each factor considered:

- (i) Whether the availability of data on which the recommended management measures are based allows for adequate

time to publish a proposed rule, and whether regulations have to be in place for an entire harvest/fishing season;

(ii) Whether there has been adequate notice and opportunity for participation by the public and members of the affected industry in the development of the Council's recommended management measures;

(iii) Whether there is an immediate need to protect the resource; and

(iv) Whether there will be a continuing evaluation of management measures adopted following their implementation as a final rule.

(3) *Regional Director action.* If the Council's recommendation includes adjustments or additions to management measures, and if after reviewing the Council's recommendation and supporting information:

(i) The Regional Director concurs with the Council's recommended management measures and determines that the recommended management measures may be published as a final rule based on the factors specified in paragraph (b)(2) of this section, the action will be published in the Federal Register as a final rule; or

(ii) The Regional Director concurs with the Council's recommendation and determines that the recommended management measures should be published first as a proposed rule, the action will be published as a proposed rule in the Federal Register. After additional public comment, if the Regional Director concurs with the Council recommendation, the action will be published as a final rule in the Federal Register; or

(iii) The Regional Director does not concur, the Council will be notified, in writing, of the reasons for the non-concurrence.

(c) Nothing in this section is meant to derogate from the authority of the Secretary of Commerce to take emergency action under section 305(e) of the Magnuson Act.

16. Figure 5 to part 651 is removed and reserved, and Figures 1, 3, and 4 to part 651 are revised to read as follows:

BILLING CODE 3510-22-W

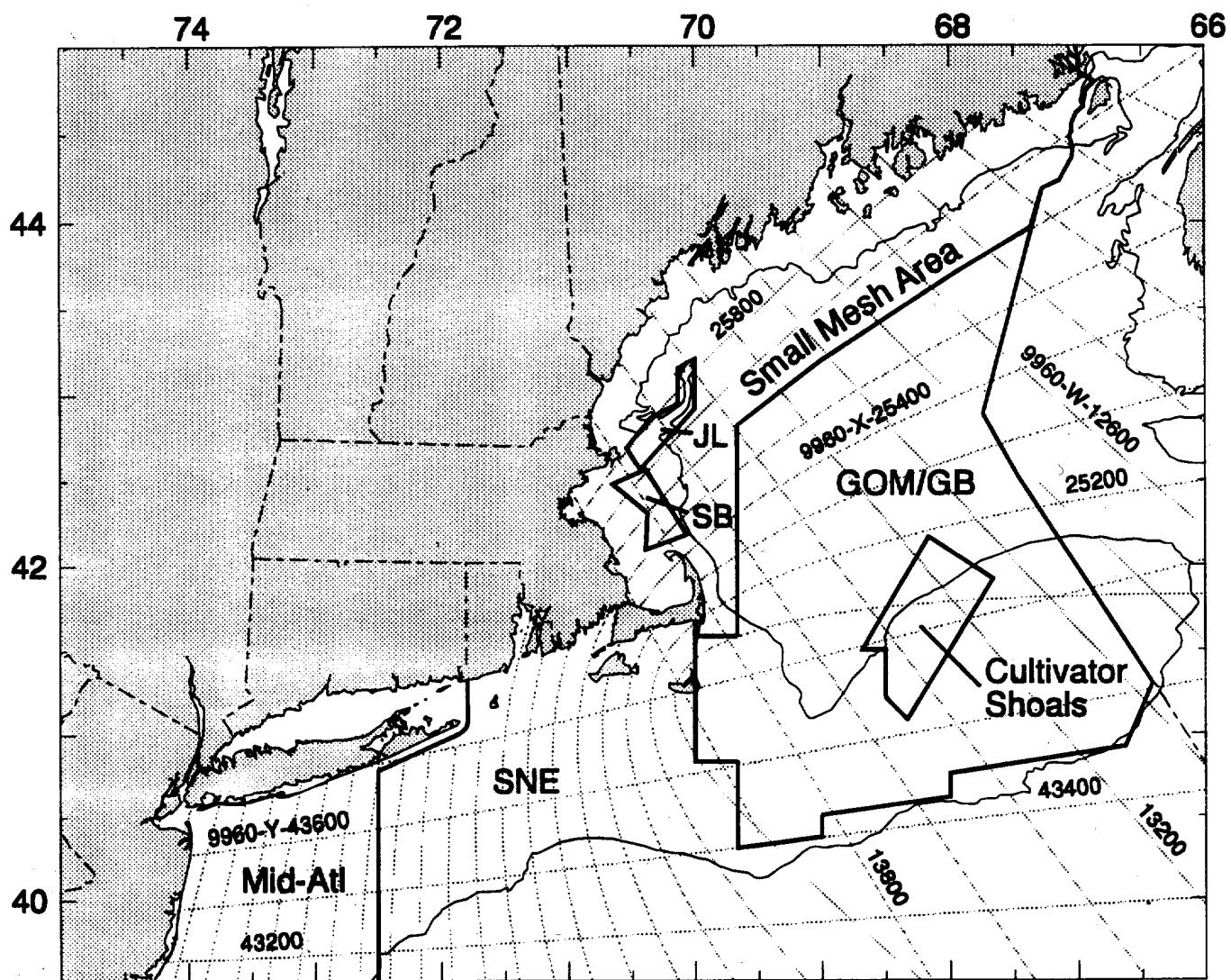


Figure 1 to part 651--Regulated Mesh Area.

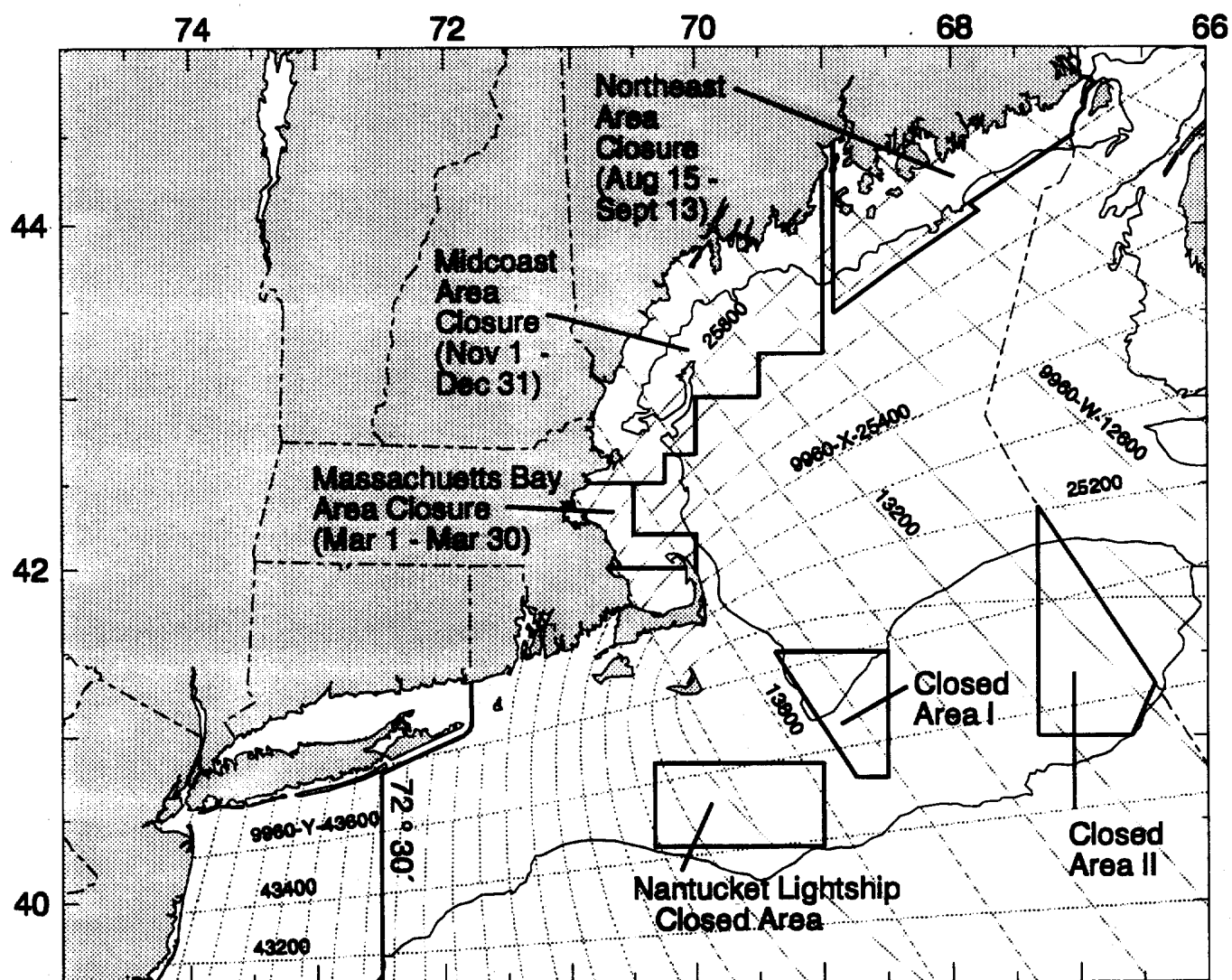


Figure 3 to part 651--Closed Areas.



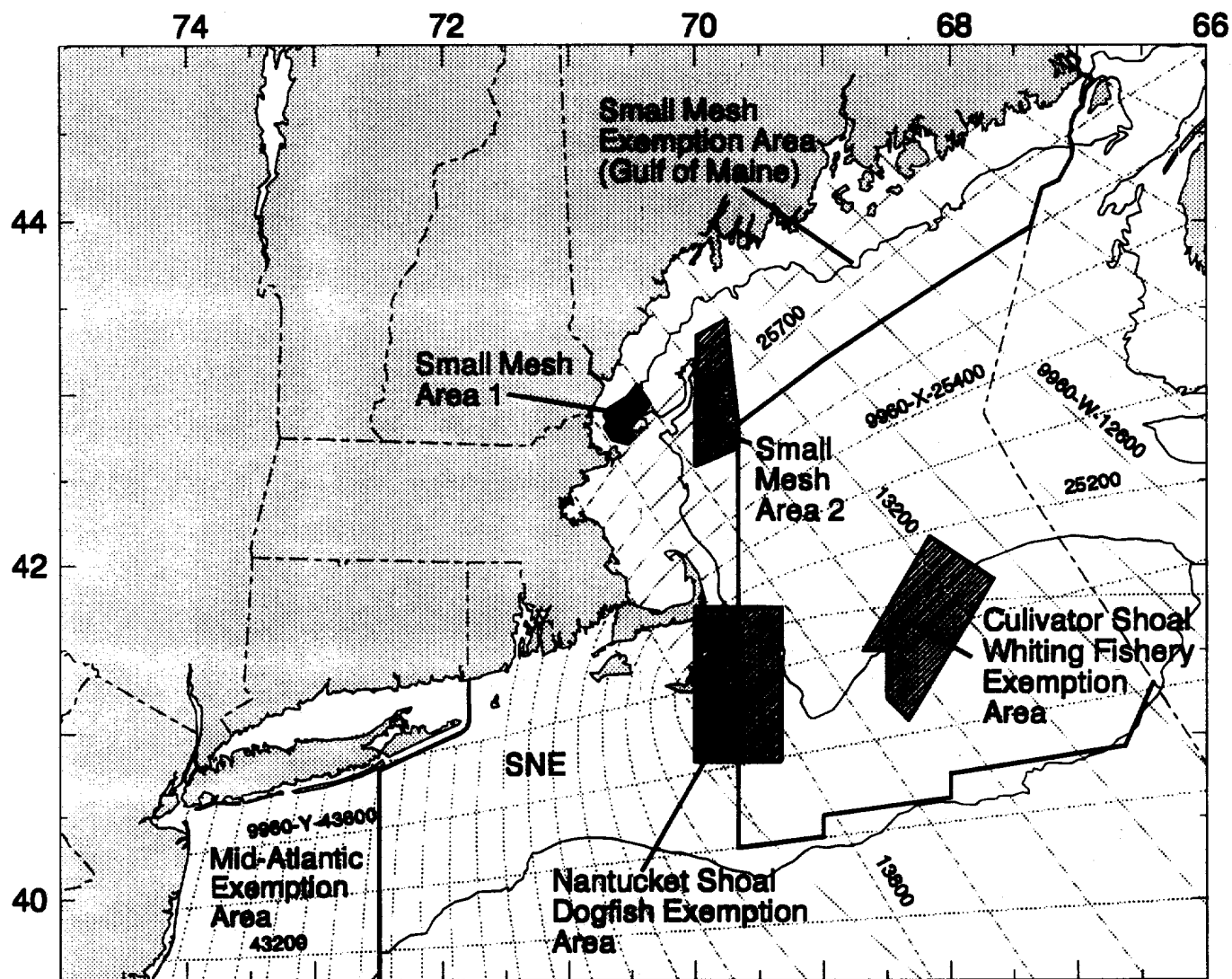


Figure 4 to part 651--Exemption Areas.

[FR Doc. 96-4709 Filed 2-29-96; 2:05 pm]

BILLING CODE 3510-22-C

**50 CFR Part 686****[I.D. 022696A]****Golden Crab Fishery Off the Southern Atlantic States; Initial Regulations**

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice of availability of a fishery management plan and request for comments.

**SUMMARY:** NMFS announces that the South Atlantic Fishery Management Council has submitted the Fishery Management Plan for the Golden Crab Fishery of the South Atlantic Region (FMP) for review, approval, and implementation by NMFS. Written comments are requested from the public.

**DATES:** Written comments must be received on or before April 25, 1996.

**ADDRESSES:** Comments must be sent to the Southeast Regional Office, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702.

Requests for copies of the FMP, which includes a regulatory impact review, a social impact assessment, and an environmental assessment, should be sent to the South Atlantic Fishery Management Council, One Southpark Circle, Suite 306, Charleston, SC 29407-4699; telephone: 803-571-4366; FAX 803-769-4520.

**FOR FURTHER INFORMATION CONTACT:** Peter J. Eldridge, 813-570-5305.

**SUPPLEMENTARY INFORMATION:** The Magnuson Fishery Conservation and Management Act (Magnuson Act) requires that a council-prepared fishery management plan (plan) be submitted to NMFS for review and approval,

disapproval, or partial disapproval. The Magnuson Act also requires that NMFS, upon receiving a plan, immediately publish a document in the Federal Register stating that the plan is available for public review and comment.

The FMP proposes to: (1) Define the management unit and optimum yield for the golden crab fishery; (2) define overfishing for species in the management unit; (3) establish a controlled access program, including initial eligibility criteria for vessel permits, restricted fishing zones, and procedures for appeals, transfers, and renewal of permits; (4) specify authorized gear for the fishery; (5) establish gear identification requirements; (6) specify maximum allowable trap sizes; (7) require escape gaps and a degradable panel on each trap; (8) establish minimum depth limits for use of traps; (9) prohibit tending of traps by unauthorized individuals; (10) modify the definition of the term "crustacean trap" in the regulations governing the South Atlantic snapper-grouper fishery (50 CFR part 646) to accommodate use of traps in the golden crab fishery; (11) prohibit the sale of female golden crabs and limit retention of female crabs to no more than 0.5 percent, by number, of all golden crabs on board the vessel; (12) require that golden crabs be landed whole; (13) limit sale of golden crab by permitted vessels to permitted golden crab dealers; (14) require that permitted golden crab dealers purchase golden crab caught in the exclusive economic zone only from permitted vessels; (15) prohibit possession of snapper-grouper species in whole, gutted, or filleted form on board a vessel fishing for or possessing golden crab; (16) establish permit and reporting requirements for fishermen

and dealers; (17) require mandatory observer coverage if a vessel is selected; and (18) establish a regulatory adjustment framework procedure to allow timely implementation of changes in the FMP's management measures.

Based on a preliminary evaluation of the FMP, the Director, Southeast Region, NMFS, (Regional Director), has disapproved a provision of the FMP that would have required 100 percent of the owners or operators of permitted vessels to maintain and submit vessel logbook information. The Regional Director believes that the methods of obtaining management data requested by the Council, and the appropriate sampling system for such data, are operational determinations properly made by NMFS. Accordingly, NMFS has determined that the level of sampling of vessels required to obtain the Council's requested data is not a matter of sufficient scope and substance warranting review under subsection 304(a)(1)(A) of the Magnuson Act. Initially, NMFS intends to select all permitted vessels to submit logbooks but may reduce the level of reporting if NMFS subsequently determines that 100 percent coverage is no longer necessary.

Proposed regulations to implement those measures of the FMP that were not disapproved based on the preliminary evaluation are scheduled for publication within 15 days.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: February 28, 1996.

Richard W. Surdi,

*Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.*

[FR Doc. 96-5015 Filed 2-29-96; 10:52 am]

**BILLING CODE 3510-22-F**

# Notices

Federal Register

Vol. 61, No. 44

Tuesday, March 5, 1996

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## DEPARTMENT OF AGRICULTURE

### Forest Service

#### **Supplemental Environmental Impact Statement for the Revised Land and Resource Management Plan, George Washington National Forest—Oil and Gas Leasing in Laurel Fork Special Management Area**

**AGENCY:** Forest Service, USDA.

**ACTION:** Notice; intent to prepare a supplemental Environmental Impact Statement.

**SUMMARY:** The Forest Service will prepare a draft and final supplement to the Final Environmental Impact Statement (FEIS) for the George Washington National Forest's Revised Land and Resource Management Plan (Forest Plan) filed in January 1993. The supplement is for a proposed action to reconsider the consent and availability decisions on oil and gas leasing in the Laurel Fork Special Management Area. This proposed action is likely to result in a nonsignificant amendment to the Forest Plan.

The agency invites written comments and suggestions that are within the scope of the proposed action and analysis for the supplement. In addition, the agency gives notice of the full environmental analysis and decision-making process that will occur on the proposal, so those interested and affected may participate in the process and contribute to the final decision.

**DATE:** A draft supplement to the FEIS is expected to be available for public comment by June 1996. Public comments on the proposal are welcome prior to the draft supplement as well.

**ADDRESSES:** Send written comments and suggestions to William E. Damon, Jr., Forest Supervisor, 5162 Valleypointe Parkway, Roanoke, VA 24019-3050.

**FOR FURTHER INFORMATION CONTACT:** Ken Landgraf, Planning Staff Officer at (540) 265-6054 or Dave Plunkett,

Interdisciplinary (ID) Team Leader at (540) 564-8300.

**SUPPLEMENTARY INFORMATION:** The Revised George Washington National Forest Land and Resource Management Plan (Forest Plan) was approved on January 21, 1993. In the Forest Plan, the agency determined that the biological and recreational values of the Laurel Fork Special Management Area (SMA) can be protected while allowing oil and gas leasing. However, the agency has now determined that these values in Laurel Fork might be better maintained and enhanced under a different management scenario. Therefore, to avoid future conflicts over management of surface and subsurface resources, the agency believes there is a need to change the Plan to more tightly focus management on these values.

Currently, the Regional Forester has given consent to the Bureau of Land Management (BLM) to lease the Laurel Fork area in the future for surface occupancy by using controlled surface use stipulations. This area was made available for leasing with such stipulations in the Revised Forest Plan.

Laurel Fork is located in the very northwest corner of Highland County, about 10 miles from Monterey, Virginia.

The agency and the public have long recognized that Laurel Fork is unique for its biological features not commonly found elsewhere in Virginia. It contains one of Virginia's finest examples of a northern boreal natural community of northern hardwoods and red spruce. At least 25 species of plants and animals have their only known occurrence within the state there. The area contains three endangered species (the federally endangered Virginia northern flying squirrel, the state endangered snowshoe hare and water shrew). These biological features make visiting the area a unique recreational experience.

The scope of this analysis is limited to the 10,000-acre Laurel Fork SMA (Management Area 21 and its associated riparian MA 18). The analysis would not cover the road corridor area (MA 7) along Forest Development Road 106; nor would it be for any other portion of the Alleghany Front Lease Area as described in the FEIS prepared for the Forest Plan (page 3-72).

Within the SMA, three leases are currently known to be issued. One BLM lease (BLM-A-0022918) is held under a Communitization Agreement (CA) for as

long as a well is considered capable of producing. Existing lease stipulations cannot be changed. Thus, the oil and gas leasing standard (Standard 21-4, Forest Plan page 3-115) in the Forest Plan does not apply to either the BLM lease or the remaining existing leases. Since these leases are already issued, their administration will be governed by post-lease procedures, specifically the Application for Permit to Drill (APD). Any new decisions about oil and gas leasing in Laurel Fork would not affect existing leases, only future leases. If the BLM lease were ever relinquished by the lessee, the subsurface area would be managed under whatever decision is reached from this analysis.

Individuals who, in the past, have indicated an interest in the Laurel Fork area and the Forest's planning process will be notified about the scope of the proposed action and about the process to identify issues. General notice to the public concerning the scope of the proposed action will also be published in a news release.

In preparing the draft supplement to the FEIS, the Forest Service will develop information pertaining to the following tentative alternatives:

1. The agency proposes to both withdraw consent to the BLM for future oil and gas leasing in the SMA and amend the Forest Plan to make Laurel Fork SMA unavailable for oil and gas leasing.

2. The agency is considering an alternative that would give consent to the BLM to lease the entire SMA with a "No Surface Occupancy" stipulation. The Forest Plan would be amended to allow this stipulation.

3. The agency is considering an alternative that would withdraw consent to the BLM to lease that portion of the SMA recognized as the Special Biological Area; but there would be no change in the consent decision for the remaining portion (east of Laurel Fork stream). This eastern area would continue to be available for surface occupancy by using controlled surface use stipulations. The Forest Plan would be amended to make the Special Biological portion of Laurel Fork unavailable for oil and gas leasing.

Alternative 8A (Revised Forest Plan), as currently discussed in the FEIS, would represent taking no action. The consent decision would remain as currently discussed in the FEIS. The

current direction in the Forest Plan would not be amended. The SMA area would continue to be available for surface occupancy by using controlled surface use stipulations.

The draft supplement to the FEIS is expected to be filed with the Environmental Protection Agency (EPA) and to be available for public review by June 1996. At that time, EPA will publish a notice of availability of the draft supplement in the Federal Register.

The comment period for the draft supplement to the FEIS will be 45 days from the date the EPA's notice of availability appears in the Federal Register. It is very important that those interested in this proposed action participate at that time. To be the most helpful, comments on the draft supplement to the environmental impact statement should be as specific as possible and may address the adequacy of the statement or the merits of the alternatives discussed (see The Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3).

In addition, Federal court decisions have established that reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewers' position and contentions. *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 553 (1978). Environmental objections that could have been raised at the draft stage may be waived if not raised until after completion of the final environmental impact statement. *City of Angoon v. Hodel*, 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc. v. Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). The reason for this is to ensure that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final.

After the comment period ends on the draft supplement, the comments will be analyzed, considered, and responded to by the Forest Service in preparing the final supplement to the environmental impact statement. The final is scheduled to be completed by September 1996. The responsible official will consider the comments, responses, environmental consequences discussed in the final supplement, and applicable laws, regulations, and policies in making a decision regarding this proposal. The responsible official will document the decision and reasons for

the decision in a Record of Decision (ROD). This ROD will be consistent with the scope of the environmental analysis in the supplement and address only the two oil and gas leasing decisions (consent and availability) within the Laurel Fork SMA. That decision will be subject to appeal under 36 CFR 217.

The Forest Service is the lead agency. The BLM will be a cooperating agency in this supplement.

The responsible official is Robert C. Joslin, Regional Forester, Southern Region, 1720 Peachtree Road, NW, Atlanta, Georgia 30367.

Dated: February 23, 1996.

Robert D. Bowers,

Acting Regional Forester.

[FR Doc. 96-5023 Filed 3-4-96; 8:45 am]

BILLING CODE 3410-11-M

### **Eldorado National Forest, CA; Notice of Intent**

**AGENCY:** Forest Service, USDA.

**ACTION:** Revision of notice of intent to prepare an Environmental Impact Statement.

**SUMMARY:** On November 7, 1989, the Forest Service filed a notice of intent in the Federal Register to prepare an environmental impact statement (EIS) to analyze management of off-highway vehicle use in the Rock Creek area, Eldorado National Forest, Georgetown Ranger District, El Dorado County, California. This notice is being filed to update that notice of intent and to notify interested parties that the Draft EIS will soon be available for comment.

**ADDRESSES:** Raymond LaBoa, District Ranger, Georgetown Ranger District, Eldorado National Forest, ATTN: Rock Creek EIS, 7600 Wentworth Springs Road, Georgetown, California 92634.

**FOR FURTHER INFORMATION CONTACT:** Direct questions about the EIS to Linda Earley, Interdisciplinary Team Leader, Georgetown Ranger District, 7600 Wentworth Springs Road, Georgetown, California 95634; phone (916) 333-4312.

**SUPPLEMENTARY INFORMATION:** Work on the EIS began in 1989 with a study of impacts to the Pacific Deer Herd. Since that time the deer study has been completed, issues identified, alternative management plans developed, and extensive data collection and analysis conducted. The Draft Rock Creek Recreational Trails EIS is now nearly complete and is expected to be released late in March 1996.

The Draft EIS analyzes alternative management plans for all types of recreation uses on the trails: hiking, equestrians, mountain bikes, and OHVs.

The need to look at all uses of the trails arose from concerns that other types of recreation use may have some of the same impacts as OHVs; as well as concerns about compatibility of uses.

Another concern identified in the analysis is open road densities which exceed limits established in the Eldorado National Forest Land and Resource management Plan (LRMP). Because the EIS analyzes road and trail densities, and because the EIS proposes designation of both open and closed roads for OHV use, it was decided that proposals for road closures to meet the LRMP management direction would be also analyzed in this EIS.

The following issues identified during scoping for this EIS were used to develop and compare alternative management plans.

1. **Erosion:** The bare soils on road and trail surfaces create a potential for erosion. The amount of erosion may be affected by total miles of roads and trails, soil type, trail location, design, maintenance, grade, vegetative cover, and use in excessively wet or dry conditions.

2. **Water Quality:** Erosion of soils can impact water quality by adding sedimentation to streams. Sedimentation may be affected by trail location and design, stream crossings, and proximity of trails to stream. Another potential impact to water quality from use of trails is the risk of oil or fuel spills at stream crossings.

3. **Wildlife Species:** Use of the trails has the potential to impact wildlife species primarily through disturbance by human presence or noise. Road and trail densities influence the potential disturbance by providing increased or decreased access into the area.

4. **Air Quality:** Air quality may be affected by emissions from motorized vehicles as well as dust from use of roads and trails.

5. **Noise:** The sound of OHVs is unacceptable to many people, and therefore may have a negative impact on adjacent landowners and the experience of other Forest users. The sound of OHV's may also contribute to disturbance of wildlife.

6. **Opportunity and Quality of the Recreation Experience:** The quality of the recreation experience may be affected by: the condition, variety, and level of challenge of the trails; the availability of staging areas and the level of development there; other uses allowed on the trails; and the aesthetics of the trail experience. Opportunity for recreation is determined by the trail mileage available and uses allowed on each; the number and size of recreation

evens allowed; and the frequency and duration of trail closures.

7. **Health and Safety:** Safety may be affected by a variety of factors. Width of trails may affect speeds traveled, and therefore risk of accidents. Intersections of roads and trails may pose increased risks of accidents. Combination of equestrian and mountain bike use of trails may pose a risk since bikes come up quietly and may startle horses. Two-way traffic poses a risk for OHVs since they cannot hear each other coming, which could result in a head-on collision. Chipsealing of road surfaces poses a risk to equestrians due to the slippery contact between the chipseal and the horseshoes. Trail structures such as gabions and cinderblocks may also pose a risk to horses. Health may be affected by availability of drinking water and sanitation facilities for recreationists; or by impacts to air quality and water quality.

8. **Risk of Fire:** Risk of fire is increased by human activity such as campfires and smoking that may be associated with use of trails. Internal combustion engines, such as OHVs also increase the risk, particularly if proper spark arresters are not in place.

9. **Funding:** Levels of funding available affects the ability to maintain trails properly, the number of trails that can be maintained, ability to construct trails, ability to effectively rehabilitate closed trails, the amount of monitoring that can be conducted, and the level of law enforcement that can be maintained. These in turn, affect the ability to implement the management plan and, therefore, to protect the environment and the quality of the recreation experience.

The following alternatives are analyzed in the Draft EIS:

*Alternative 1—No Action:*

This alternative would continue the current management of the Rock Creek Trails. Most trails in the area are multiple use, open to all four use types: hiking, equestrians, mountain bikes, and OHVs. There are approximately 140 miles of multiple use routes (roads and trails) and 5 miles of routes restricted to non-motorized uses. The current management plan includes closure of the Critical Deer Winter Range to OHVs and mountain bikes from November 1 to May 1 each year. Trails are also closed to OHVs during wet weather conditions.

*Alternative 2—No OHV Use:* OHV use would be eliminated in this alternative. There would be approximately 46 miles of non-motorized routes available. Approximately 31 miles of roads would be closed. Trails would be closed to equestrians and mountain bikes during wet weather conditions, and staging

areas in the Critical Deer Winter Range would be closed from February 1 to May 1. Up to two large recreation events, with up to 300 participants, would be allowed each year for each non-motorized use type.

*Alternative 3—Increased Multiple Use Recreation:* This alternative reduces trail closures and allows the maximum trail density. Approximately 141 miles of multiple use routes would be available, and 15 miles of non-motorized routes. Approximately 28 miles of roads would be closed. There would be no closure of the Critical Deer Winter Range. Wet weather closures would apply to OHVs, equestrians, and mountain bikes, but an all-season route would be provided that could be used during those closures. Up to two large recreation events per year, with up to 500 participants each, would be allowed for each use type.

*Alternative 4—Separated Multiple Use Recreation:* This alternative addresses concerns about shared use of trails by different types of uses. The system would include approximately 84 miles of multiple use routes, 17 miles of non-motorized routes, 5 miles of hiking only routes, and 11 miles of hiking and equestrian routes. Approximately 26 miles of roads would be closed. Staging areas in the Critical Deer Winter Range would be closed from February 1 to May 1. Trails would be closed to OHVs, equestrians, and mountain bikes during wet weather conditions. One large recreation event would be allowed per year for each use type, with up to 300 participants in each.

*Alternative 5—Reduced Multiple Use Recreation:* This alternative includes approximately 69 miles of multiple use routes and 29 miles of non-motorized routes. Approximately 32 miles of roads would be closed. Routes in the Critical Deer Winter Range would be closed to all uses from November 10 to May 1 of each year. Roads and trails would be closed to OHVs, equestrians, and mountain bikes during the Forest seasonal road closures (generally November through March). Trails would be closed to OHVs during Forest fire restrictions (generally August and September). Large recreation events with over 75 people involved would be prohibited.

*Alternative 6—"Carrying Capacity" Alternative:* This alternative was developed based on a review of effects of other alternatives. The goal of the alternative is to maximize recreation opportunity while providing protection of the natural resources. The system would include approximately 108 miles of multiple use routes, and 13 miles of non-motorized routes. Approximately

32 miles of roads would be closed. Routes in the Critical Deer Winter Range would be closed to all uses from December 1 to May 1 each year, with the exception of an all-season route which traverses the area. Routes would be closed to OHVs, equestrians, and mountain bikes during wet weather conditions with the exception of the all season routes. Up to two recreation events, with up to 300 participants, would be allowed each year for each type of use.

Raymond LaBoa, District Ranger, Georgetown Ranger District, Eldorado National Forest, is the responsible official.

The draft EIS is expected to be filed with the Environmental Protection Agency (EPA) and to be available for public review in late March 1996. At that time the EPA will publish a notice of availability of the draft EIS in the Federal Register.

The comment period on the draft EIS will be 45 days from the date EPA's notice of availability appears in the Federal Register. It is very important that reviewers participate at that time. To be the most helpful, comments on the draft EIS should be as specific as possible and may address the adequacy of the statement or the merits of the alternatives discussed (see The Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3). In addition, Federal court decisions have established that reviewers of draft EIS's must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewers' position and contentions, *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 553 (1978), and that environmental objections that could have been raised at the draft stage may be waived if not raised until after completion of the final EIS. *Wisconsin Heritages, Inc. v. Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). The reason for this is to ensure that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final EIS.

After the comment period ends on the draft EIS, the comments will be analyzed and considered by the Forest Service in preparing the final EIS. The final EIS is scheduled to be completed by September 1996. The Forest Service is required to respond in the final EIS to the comments received (40 CFR 1503.4). The responsible official will consider the comments, responses, disclosure of environmental

consequences, and applicable laws, regulations, and policies in making a decision regarding this proposal. The responsible official will document the decision and rationale in the Record of Decision. That decision will be subject to appeal.

Dated: February 23, 1996.

Raymond E. LaBoa,  
*District Ranger, Georgetown Ranger District,  
Eldorado National Forest.*

[FR Doc. 96-5085 Filed 3-4-96; 8:45 am]

BILLING CODE 3410-11-M

## DEPARTMENT OF COMMERCE

### National Institute of Standards and Technology

#### Computer System Security and Privacy Advisory Board, Meeting

**AGENCY:** National Institute of Standards and Technology, Commerce.

**ACTION:** Notice of meeting.

**SUMMARY:** Pursuant to the Federal Advisory Committee Act, 5 U.S.C. App., notice is hereby given that the Computer System Security and Privacy Advisory Board will meet Wednesday, March 27 and Thursday, March 28, 1996 from 9:00 a.m. to 5:00 p.m. The Advisory Board was established by the Computer Security Act of 1987 (P.L. 100-235) to advise the Secretary of Commerce and the Director of NIST on security and privacy issues pertaining to federal computer systems. All sessions will be open to the public.

**DATES:** The meeting will be held on March 27 and 28, 1996 from 9:00 a.m. to 5:00 p.m.

**ADDRESSES:** The meeting will take place at the National Institute of Standards and Technology, Gaithersburg, Maryland 20899-0001.

#### Agenda:

- Welcome, Introduction of New Members, and Overview
- Issues Update
- Encryption Update
- Telecommuting Security Issues
- NARA E-Mail Policy Briefing
- Pending Business
- Public Participation
- Agenda development for June meeting
- Wrap-Up

Public participation: The Board agenda will include a period of time, not to exceed thirty minutes, for oral comments and questions from the public. Each speaker will be limited to five minutes. Members of the public who are interested in speaking are asked to contact the Board Secretariat at the

telephone number indicated below. In addition, written statements are invited and may be submitted to the Board at any time. Written statements should be directed to the Computer Systems Laboratory, Building 820, Room 426, National Institute of Standards and Technology, Gaithersburg, MD 20899-0001. It would be appreciated if fifteen copies of written material were submitted for distribution to the Board by March 11, 1996. Approximately 20 seats will be available for the public and media.

#### FOR FURTHER INFORMATION CONTACT:

Mr. Edward Roback, Board Secretariat, Computer Systems Laboratory, National Institute of Standards and Technology, Building 820, Room 426, Gaithersburg, MD 20899-0001, telephone: (301) 975-3696.

Dated: February 27, 1996.

Samuel Kramer,  
*Associate Director.*

[FR Doc. 96-5027 Filed 3-4-96; 8:45 am]

BILLING CODE 3510-13-M

### National Oceanic and Atmospheric Administration

[I.D. 022796A]

#### Mid-Atlantic Fishery Management Council; Meetings

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice of public meetings.

**SUMMARY:** The Mid-Atlantic Fishery Management Council's Squid, Mackerel, Butterfish Committee and Large Pelagics Committee will hold public meetings.

**DATES:** The meetings will be held on March 19, 1996. The Squid, Mackerel, Butterfish Committee will meet from 9:30 a.m. until 1:00 p.m. The Large Pelagics Committee will meet from 2:00 p.m. until 5:00 p.m.

**ADDRESSES:** The meetings will be held at the Days Inn (at airport), 4101 Island Avenue, Philadelphia, PA; telephone: (215) 492-0400.

*Council Address:* Mid-Atlantic Fishery Management Council, 300 S. New Street, Dover, DE 19901; telephone: (302) 674-2331.

#### FOR FURTHER INFORMATION CONTACT:

David R. Keifer, Executive Director; telephone: (302) 674-2331.

**SUPPLEMENTARY INFORMATION:** The purpose of these meetings is to review material prepared by staff for resubmission of Amendment 5 to the Squid, Mackerel, Butterfish Plan, and to

discuss the quota for large coastal sharks and issues related to Atlantic tunas and swordfish.

#### Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Joanna Davis at (302) 674-2331 at least 5 days prior to the meeting date.

Dated: February 28, 1996.

Richard W. Surdi,

*Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.*

[FR Doc. 96-5099 Filed 3-4-96; 8:45 am]

BILLING CODE 3510-22-F

[I.D. 022796B]

### Endangered Species; Permits

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Receipt of applications for a scientific research permit (P770#70) and modifications to two scientific research permits (P563A and P510).

**SUMMARY:** Notice is hereby given that the Coastal Zone and Estuarine Studies Division, NMFS, in Seattle, WA (CZESD) has applied in due form for a permit and the Northern Wasco County People's Utility District in The Dalles, OR (NWCPUD) and the Shoshone-Bannock Tribes in Fort Hall, ID (SBT) have applied in due form for modifications to permits to take endangered and threatened species for the purpose of scientific research.

**DATES:** Written comments or requests for a public hearing on any of these applications must be received on or before April 4, 1996.

**ADDRESSES:** The applications and related documents are available for review in the following offices, by appointment:

Office of Protected Resources, F/PR8, NMFS, 1315 East-West Highway, Silver Spring, MD 20910-3226 (301-713-1401); and

Environmental and Technical Services Division, 525 NE Oregon Street, Suite 500, Portland, OR 97232-4169 (503-230-5400).

Written comments or requests for a public hearing should be submitted to the Chief, Endangered Species Division, Office of Protected Resources.

**SUPPLEMENTARY INFORMATION:** CZESD requests a permit and NWCPUD and SBT request modifications to permits

under the authority of section 10 of the Endangered Species Act of 1973 (ESA) (16 U.S.C. 1531-1543) and the NMFS regulations governing listed fish and wildlife permits (50 CFR parts 217-227).

CZESD (P770#70) requests a 3-year permit to directly take juvenile, threatened, Snake River spring/summer and fall chinook salmon (*Oncorhynchus tshawytscha*) and juvenile, endangered, Snake River sockeye salmon (*Oncorhynchus nerka*) and to indirectly take juvenile, threatened, Snake River spring/summer and fall chinook salmon and juvenile, endangered, Snake River sockeye salmon associated with four studies designed to evaluate existing and proposed juvenile fish bypass systems at four hydroelectric dams on the Snake and Columbia Rivers. Study 1 will evaluate the new juvenile bypass facility at Ice Harbor Dam. Listed juvenile fish are proposed to be collected and sacrificed for blood chemical analysis as a means to measure stress reaction to stimulus experienced by fish at the facility. A greater proportion of listed juvenile fish are proposed to be indirectly captured and released to acquire the juvenile fish to be sacrificed for the study. The take associated with Study 1 is requested annually for three years.

Studies 2-4 will evaluate the effectiveness of juvenile fish guidance devices and other important bypass system components at Little Goose Dam, McNary Dam, and John Day Dam respectively. A proportion of the listed juvenile fish that are successfully diverted from hydropower turbines are proposed to be captured, anesthetized, examined, counted, allowed to recover from the anesthetic, and released. A proportion of the listed juvenile fish that fail to enter the fish bypass system at John Day Dam only (Study 4) are proposed to be captured and sacrificed. Some indirect mortalities of the listed juvenile fish proposed to be taken for Studies 2-4 are likely to occur. The takes associated with Studies 2-4 are requested for 1996 only.

NWCPUD (P563A) requests modification 1 to permit 948 for an increase in their authorized annual take of ESA-listed species associated with scientific research and monitoring activities. Permit 948 authorizes a take of juvenile, endangered, Snake River sockeye salmon (*Oncorhynchus nerka*); juvenile, threatened, naturally-produced and artificially-propagated, Snake River spring/summer chinook salmon (*Oncorhynchus tshawytscha*); and juvenile, threatened, Snake River fall chinook salmon (*Oncorhynchus tshawytscha*) associated with an annual study designed to assess run-of-the-river

juvenile anadromous fish condition after passage through the screened turbine intake channel at The Dalles Dam, located on the Columbia River. A greater number of juvenile, listed, artificially-propagated, Snake River spring/summer chinook salmon and juvenile, listed, Snake River fall chinook salmon are requested to be captured and handled, with a corresponding increase in the number of indirect mortalities, as a result of NMFS's 1996 juvenile outmigration estimates. Modification 1 is requested for the duration of the permit. Permit 948 expires on September 30, 1999.

SBT (P510) requests modification 3 to scientific research permit 849. Permit 849 authorizes a take of adult and juvenile, threatened, Snake River spring/summer chinook salmon associated with stock assessment and fish condition surveys in the Salmon River subbasin and the pond series of Yankee Fork, Salmon River in Idaho. For modification 3, SBT requests to expand the area of their electrofishing research to include the Salmon River subbasin, an area previously unspecified for this research activity. Modification 3 would be valid for the duration of the permit. Permit 849 expires on November 30, 1997.

Those individuals requesting a hearing (see ADDRESSES) should set out the specific reasons why a hearing on any of these applications would be appropriate. The holding of such hearing is at the discretion of the Assistant Administrator for Fisheries, NOAA. All statements and opinions contained in these application summaries are those of the applicants and do not necessarily reflect the views of NMFS.

Dated: February 27, 1996.

Russell J. Bellmer,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 96-4998 Filed 3-4-96; 8:45 am]

BILLING CODE 3510-22-P

## COUNCIL ON ENVIRONMENTAL QUALITY

**Operational Summary of Grayrocks Reservoir and Water Usage of the Laramie River Station, 16th Annual Report, for the Water Year Ending September 30, 1995, published in conjunction with the Endangered Species Act exemption granted to Grayrocks Dam and Reservoir by the Endangered Species Committee in February, 1979**

### FOR FURTHER INFORMATION CONTACT:

Dinah Bear, General Counsel, Council on Environmental Quality, 722 Jackson Place, N.W., Washington, D.C. 20503. Telephone: 202/395-5750.

Elisabeth Blaug,

Associate General Counsel, Council on Environmental Quality.

Operational Summary of Grayrocks Reservoir and Water Usage of the Laramie River Station—16th Annual Report For the Water Year Ending September 30, 1995

### Purpose of Report

In compliance with the AGREEMENT OF SETTLEMENT AND COMPROMISE, the Missouri Basin Power Project has agreed to submit an annual report to all signed parties of the AGREEMENT OF SETTLEMENT AND COMPROMISE concerning the operation of Grayrocks Reservoir. This report provides data gathered from metering and gaging stations pertinent to the operation and administration of Grayrocks Reservoir and the Laramie River Station in compliance with the AGREEMENT OF SETTLEMENT AND COMPROMISE.

### Report of Operation

The 1994-1995 water year started out as another drought year; from October 1, 1994 until March 25, 1995 Grayrocks Reservoir only gained 300.0 acre feet in storage. From March 25, 1995 to May 8, 1995 Grayrocks Reservoir storage decreased 2000.0 acre feet. However, spring and earlier summer rain and snow kept the Laramie River inflow to Grayrocks Reservoir above 300.0 cfs from May 8 until July 12.

Grayrocks Reservoir physically filled (104,109 acre feet) on June 6, 1995 and reached a peak storage of 110,603 acre feet on June 10, 1995. The peak inflow to Grayrocks Reservoir occurred on June 8 with a flow of 4220.0 cfs; the peak release from Grayrocks Reservoir occurred on June 10 with a flow of 3038.0 cfs as measured at Grayrocks Reservoir outflow gage.

Grayrocks Reservoir storage on September 30, 1995 was 99,217 acre feet (1.4 feet from being physically filled).



The following is a chronological summary of major occurrences during the operation of Grayrocks Dam and Reservoir for the 1994–1995 water year.

October 1, 1994—Began year with 74,840 acre feet in storage.

October 31, 1994—October releases approximately 40.0 acre feet in excess of "Agreement" as measured at Grayrocks Outflow Gage and 602.0 acre feet in excess of "Agreement" as measured at the Fort Laramie Gage.

November 30, 1994—November releases approximately 95.0 acre feet in excess of "Agreement" as measured at Grayrocks Outflow Gage and 285.0 acre feet in excess of "Agreement" as measured at the Fort Laramie Gage.

December 31, 1994—December releases approximately 37.0 acre feet in excess of "Agreement" as measured at Grayrocks Outflow Gage and 143.0 acre feet in excess of "Agreement" as measured at the Fort Laramie Gage.

January 31, 1995—January releases approximately 159.0 acre feet in excess of "Agreement" as measured at Grayrocks Outflow Gage and 293.0 acre feet in excess of "Agreement" as measured at the Fort Laramie Gage.

February 28, 1995—February releases approximately 60.0 acre feet in excess of "Agreement" as measured at Grayrocks Outflow Gage and 206.0 acre feet in excess of "Agreement" as measured at the Fort Laramie Gage.

March 31, 1995—March releases approximately 36.0 acre feet in excess of "Agreement" as measured at Grayrocks Outflow Gage and 64.0 acre feet in excess of "Agreement" as measured at the Fort Laramie Gage.

April 1, 1995—Increased releases to 50 cfs according to "Agreement".

April 30, 1995—April releases approximately 456.0 acre feet in excess of "Agreement" as measured at Grayrocks Outflow Gage and 118.0 acre feet in excess of "Agreement" as measured at the Fort Laramie Gage.

Grayrocks Reservoir minimum storage for year; 72,786 acre feet.

May 1, 1995—Maintaining Grayrocks Reservoir releases at 40 cfs or 75% of the inflow which ever is greater not to exceed 200 cfs nor more than 12,000 acre feet per month.

May 8, 1995—Grayrocks Reservoir inflow over 300.0 cfs.

May 12, 1995—Grayrocks Reservoir releases over 200.0 cfs.

May 19, 1995—Grayrocks Reservoir inflow over 500.0 cfs.

May 27, 1995—Grayrocks Reservoir inflow over 1000.0 cfs.

May 30, 1995—May releases approximately 298.0 acre feet in excess of "Agreement" as measured at Grayrocks Outflow Gage and 2.0 acre

feet in excess of "Agreement" as measured at the Fort Laramie Gage.

June 3, 1995—Grayrocks Reservoir inflow over 1600.0 cfs. Grayrocks Reservoir releases over 300.0 cfs.

June 4, 1995—Grayrocks Reservoir releases over 400.0 cfs.

June 6, 1995—Grayrocks Reservoir releases over 600.0 cfs.

June 7, 1995—Grayrocks Reservoir releases over 800.0 cfs.

June 8, 1995—Grayrocks Reservoir peak inflow 4220.0 cfs (24 hour average). Grayrocks Reservoir releases over 2000.0 cfs.

June 9, 1995—Grayrocks Reservoir releases over 3000.0 cfs.

June 12, 1995—Grayrocks Reservoir inflow below 3000.0 cfs. Grayrocks Reservoir releases below 3000.0 cfs.

June 14, 1995—Grayrocks Reservoir inflow below 2000.0 cfs.

June 15, 1995—Grayrocks Reservoir releases below 2000.0 cfs.

June 16, 1995—Grayrocks Reservoir inflow below 1500.0 cfs.

June 20, 1995—Grayrocks Reservoir releases below 1000.0 cfs.

June 26, 1995—Grayrocks Reservoir inflow below 1000.0 cfs.

June 30, 1995—June releases approximately 59,500.0 acre feet in excess of "Agreement" as measured at Grayrocks Outflow Gage and 52,088.0 acre feet in excess of "Agreement" as measured at the Fort Laramie Gage.

July 7, 1995—Grayrocks Reservoir releases below 500.0 cfs.

July 9, 1995—Grayrocks Reservoir inflow below 500.0 cfs.

July 19, 1995—Grayrocks Reservoir inflow below 200.0 cfs. Grayrocks Reservoir releases below 200.0 cfs.

July 27, 1995—Grayrocks Reservoir inflow below 100.0 cfs.

July 28, 1995—Grayrocks Reservoir releases below 100.0 cfs.

July 31, 1995—July releases approximately 10,400.0 acre feet in excess of "Agreement" as measured at Grayrocks Outflow Gage and 10,000.0 acre feet in excess of "Agreement" as measured at the Fort Laramie Gage.

August 31, 1995—August releases approximately 950.0 acre feet in excess of "Agreement" as measured at Grayrocks Outflow Gage and 438.0 acre feet in excess of "Agreement" as measured at the Fort Laramie Gage.

September 30, 1995—September releases approximately 520.0 acre feet in excess of "Agreement" as measured at Grayrocks Outflow Gage and 595.0 acre feet in excess of "Agreement" as measured at the Fort Laramie Gage.

Grayrocks Reservoir end of year storage at 99,217 acre feet (1.4 feet from being filled).

On April 13, 1995 when the Boughton Water Transfer came into priority, there

was only 1.0 cfs at the Bosler Gage. Until the spring rain and snow showers came with the resulting runoff, there was not any water available for the Boughton Water Transfer right. Then with the high runoff and Grayrocks Reservoir being filled, no Boughton Water was transferred. The Inundated Water rights were fully utilized.

During the 1994–1995 year, releases from Grayrocks Reservoirs totaled approximately 126,421.95 acre feet as measured at Grayrocks outflow gage; at the Ft. Laramie Gage the releases total approximately 118,689.42 acre feet. The releases called for in the "AGREEMENT OF SETTLEMENT AND COMPROMISE" were approximately 53,833.50 acre feet for the 1994–1995 water year.

The Laramie River Station water usage for 1994–1995 water year totaled 17,591.43 acre feet, gross generation was 11,420,657 megawatts, and the net generation was 10,706,705 megawatts. With two unit outages this year the Laramie River Station plant factor was 74%.

Attached are the "Laramie River Station Water Sources and Station Usage Monthly Reports and Annual Summary" for the 1994–1995 Water Year.

#### BASIN ELECTRIC POWER COOPERATIVE—LARAMIE RIVER STATION WATER SOURCES AND STATION USAGE ANNUAL SUMMARY FOR 1994–1995

Grayrocks inflows:		
Boughton water at Bosler .....	AF	0.00
Conveyance loss Bosler to Grayrocks .....	AF	0.00
Laramie River above Grayrocks Boughton water at Grayrocks .....	AF	191,356.77
Inundated water rights .....	AF	0.00
Natural flow above Grayrocks .....	AF	1,647.28
Senior downstream rights .....	AF	189,689.23
Water available to Grayrocks .....	AF	0.00
Grayrocks releases:		
Laramie River below Grayrocks Laramie River at Fort Laramie .....	AF	126,421.95
Bypass for senior rights .....	AF	118,689.42
Releases charged again storage .....	AF	0.00
Flood storage releases .....	AF	33,191.90
Physical spill .....	AF	4,557.21
LRS water usage: Inundated water to LRS .....	AF	93,214.16
	AF	1,473.97



BASIN ELECTRIC POWER COOPERATIVE—LARAMIE RIVER STATION  
WATER SOURCES AND STATION  
USAGE ANNUAL SUMMARY FOR  
1994–1995—Continued

Inundated water to temporary storage .....	AF	173.23
Boughton water to LRS .....	AF	0.00
Boughton water to temporary storage .....	AF	0.00
Direct diversion to LRS .....	AF	15,914.96
Temporary storage to LRS .....	AF	199.29
Permanent storage to LRS .....	AF	0.00

BASIN ELECTRIC POWER COOPERATIVE—LARAMIE RIVER STATION  
WATER SOURCES AND STATION  
USAGE ANNUAL SUMMARY FOR  
1994–1995—Continued

Red well water to LRS .....	AF	1.76
Green well water to LRS .....	AF	1.45
Total water to LRS .....	AF	17,591.43
Grayrocks Reservoir storage accounting:		
Ending reservoir elevation .....	FT	4,402.60
Reservoir evaporation .....	AF	12,398.43

BASIN ELECTRIC POWER COOPERATIVE—LARAMIE RIVER STATION  
WATER SOURCES AND STATION  
USAGE ANNUAL SUMMARY FOR  
1994–1995—Continued

Evaporation loss for temporary storage .....	AF	41.72
Transferred water to temporary storage .....	AF	173.23
Direct flow to permanent storage ..	AF	43,879.66
Direct flow to flood storage .....	AF	17,166.77
Ending physical storage .....	AF	99,217.00
Agreements required releases .....	AF	53,833.50

GRAYROCKS RESERVOIR STORAGE IN ACRE FEET FOR 1994–1995 WATER YEAR

	Oct.	Nov.	Dec.	Jan.	Feb.	Mar.	Apr.	May	Jun.	Jul.	Aug.	Sept.
1 .....	74,840	73,373	72,493	72,786	73,666	74,253	74,547	72,786	93,769	107,332	105,541	101,650
2 .....		73,080							94,783	106,974		101,299
3 .....									96,135		105,183	100,947
4 .....						74,547			98,183	106,616		100,596
5 .....		72,786	72,199		73,960		74,253		101,299	106,258		
6 .....								73,080	104,109			100,251
7 .....	74,547	73,080				74,840			105,900	106,616	105,183	99,907
8 .....	74,253							73,666	106,974			
9 .....				73,080			73,960	74,253	109,875		104,825	
10 .....								74,840	110,603	106,974		
11 .....					73,666			75,140	110,239	106,616		
12 .....				73,373		75,140		74,840	109,875	106,974		98,873
13 .....								75,739	108,418	106,616		
14 .....	73,960		72,493				73,666	76,039	106,616	106,258	104,467	
15 .....									106,258			
16 .....		72,786			73,373			76,339	105,900		104,109	98,528
17 .....	74,253				73,666			76,639	105,541			
18 .....								76,939	105,183			
19 .....							73,373	77,538	105,541	105,900	103,758	
20 .....				73,666	73,960			78,144				
21 .....	73,960		72,786					79,062	105,183		103,406	
22 .....	73,666							79,674	105,541			
23 .....								80,286		106,258		
24 .....				73,373				81,210	105,900	105,900	103,055	
25 .....					74,253	74,840	73,080	82,460	105,541			
26 .....		72,493		73,666				83,709			102,704	98,873
27 .....	73,373							84,977	105,183			
28 .....					74,253			86,888	106,616		102,353	
29 .....						74,547		88,831	106,974	105,541	102,001	99,217
30 .....						74,840	72,786	90,786	107,690			99,217
31 .....	73,373	72,493	72,786	73,666		74,840		92,443		105,541	101,650	

BASIN ELECTRIC POWER COOPERATIVE—LARAMIE RIVER STATION WATER SOURCES AND STATION USAGE MONTHLY  
REPORT

SEPTEMBER 1995		
Grayrocks Inflows:		
Boughton water at Bosler .....	AF	0
Conveyance loss Bosler to Grayrocks .....	AF	0
Laramie River above Grayrocks .....	AF	3,684.35
Boughton water at Grayrocks .....	AF	0
Inundated water rights .....	AF	32.21
Natural flow above Grayrocks .....	AF	3,652.14
Senior downstream rights .....	AF	0
Water available to Grayrocks .....	AF	3,652.14
Grayrocks Downstream Release:		
Laramie River below Grayrocks .....	AF	2,904.44
Laramie River at Ft. Laramie .....	AF	2,975.05
Bypass for senior rights .....	AF	0

**BASIN ELECTRIC POWER COOPERATIVE—LARAMIE RIVER STATION WATER SOURCES AND STATION USEAGE MONTHLY  
REPORT—Continued**

Releases charged against storage .....	AF	0
Water for storage or diversion .....	AF	3,652.14
Flood storage releases .....	AF	0
Physical spill .....	AF	2,904.44
LRS Water Useage:		
Inundated water to LRS .....	AF	32.18
Inundated water to temporary storage .....	AF	0.03
Boughton water to LRS .....	AF	0
Boughton water to temporary storage .....	AF	0
Direct diversion to LRS .....	AF	1,032.62
Temporary storage to LRS .....	AF	47.69
Permanent storage to LRS .....	AF	0
Red Well water to LRS .....	AF	0
Green Well water to LRS .....	AF	0
Total water to LRS .....	AF	1,112.49
Grayrocks Reservoir Storage Accounting:		
Ending reservoir elevation .....	FT	4402.6
Reservoir evaporation .....	AF	808.40
Evap. loss for temporary storage .....	AF	2.08
Trans. water to temporary storage .....	AF	0.03
Direct diversion to perm. storage .....	AF	2,619.52
Direct diversion to flood storage .....	AF	0
Ending physical storage .....	AF	99,217
Total required releases .....	AF	2,380.20
AUGUST 1995		
Grayrocks Inflows:		
Boughton water at Bosler .....	AF	0
Conveyance loss Bosler to Grayrocks .....	AF	0
Laramie River above Grayrocks .....	AF	2,984.18
Boughton water at Grayrocks .....	AF	0
Inundated water rights .....	AF	407.05
Natural flow above Grayrocks .....	AF	2,577.12
Senior downstream rights .....	AF	0
Water available to Grayrocks .....	AF	2,577.12
Grayrocks Downstream Release:		
Laramie River below Grayrocks .....	AF	3,631.19
Laramie River at Ft. Laramie .....	AF	3,111.71
Bypass for senior rights .....	AF	0
Releases charged against storage .....	AF	0
Water for storage or diversion .....	AF	2,577.12
Flood storage releases .....	AF	534.89
Physical spill .....	AF	3,631.18
LRS Water Useage:		
Inundated water to LRS .....	AF	399.28
Inundated water to temporary storage .....	AF	7.75
Boughton water to LRS .....	AF	0
Boughton water to temporary storage .....	AF	0
Direct diversion to LRS .....	AF	1,415.96
Temporary storage to LRS .....	AF	87.54
Permanent storage to LRS .....	AF	0
Red Well water to LRS .....	AF	0
Green Well water to LRS .....	AF	0
Total water to LRS .....	AF	1,902.78
Grayrocks Reservoir Storage Accounting:		
Ending reservoir elevation .....	FT	4403.3
Reservoir evaporation .....	AF	6,580.39
Evap. loss for temporary storage .....	AF	22.10
Trans. water to temporary storage .....	AF	7.75
Direct diversion to perm. storage .....	AF	230.55
Direct diversion to flood storage .....	AF	50.27
Ending physical storage .....	AF	101,650
Total required releases .....	AF	2,672.83
JULY 1995		
Grayrocks Inflows:		
Boughton water at Bosler .....	AF	0

**BASIN ELECTRIC POWER COOPERATIVE—LARAMIE RIVER STATION WATER SOURCES AND STATION USEAGE MONTHLY  
REPORT—Continued**

Conveyance loss Bosler to Grayrocks .....	AF	0
Laramie River above Grayrocks .....	AF	20,847.58
Boughton water at Grayrocks .....	AF	0
Inundated water rights .....	AF	407.05
Natural flow above Grayrocks .....	AF	20,440.52
Senior downstream rights .....	AF	0
Water available to Grayrocks .....	AF	20,440.52
Grayrocks Downstream Release:		
Laramie River below Grayrocks .....	AF	19,622.57
Laramie River at Ft. Laramie .....	AF	19,231.02
Bypass for senior rights .....	AF	0
Releases charged against storage .....	AF	0
Water for storage or diversion .....	AF	20,440.52
Flood storage releases .....	AF	1,551.91
Physical spill .....	AF	19,622.55
LRS Water Usage:		
Inundated water to LRS .....	AF	393.90
Inundated water to temporary storage .....	AF	13.13
Boughton water to LRS .....	AF	0
Boughton water to temporary storage .....	AF	0
Direct diversion to LRS .....	AF	1,368.43
Temporary storage to LRS .....	AF	0
Permanent storage to LRS .....	AF	0
Red Well water to LRS .....	AF	0
Green Well water to LRS .....	AF	0
Total water to LRS .....	AF	1,762.33
Grayrocks Reservoir Storage Accounting:		
Ending reservoir elevation .....	FT	4404.4
Reservoir evaporation .....	AF	1,911.05
Evap. loss for temporary storage .....	AF	6.98
Trans. water to temporary storage .....	AF	13.13
Direct diversion to perm. storage .....	AF	0
Direct diversion to flood storage .....	AF	1,001.41
Ending physical storage .....	AF	105,541
Total required releases .....	AF	9,213.00
JUNE 1995		
Grayrocks Inflows:		
Boughton water at Bosler .....	AF	0
Conveyance loss Bosler to Grayrocks .....	AF	0
Laramie River above Grayrocks .....	AF	101,386.60
Boughton water at Grayrocks .....	AF	0
Inundated water rights .....	AF	393.92
Natural flow above Grayrocks .....	AF	100,992.68
Senior downstream rights .....	AF	0
Water available to Grayrocks .....	AF	100,992.68
Grayrocks Downstream Release:		
Laramie River below Grayrocks .....	AF	71,412.94
Laramie River at Ft. Laramie .....	AF	63,989.30
Bypass for senior rights .....	AF	0
Releases charged against storage .....	AF	4,562.05
Water for storage or diversion .....	AF	100,992.68
Flood storage releases .....	AF	2,470.41
Physical spill .....	AF	66,850.90
LRS Water Usage:		
Inundated water to LRS .....	AF	338.48
Inundated water to temporary storage .....	AF	55.42
Boughton water to LRS .....	AF	0
Boughton water to temporary storage .....	AF	0
Direct diversion to LRS .....	AF	1,057.61
Temporary storage to LRS .....	AF	0
Permanent storage to LRS .....	AF	0
Red Well water to LRS .....	AF	0
Green Well water to LRS .....	AF	0
Total water to LRS .....	AF	1,396.09
Grayrocks Reservoir Storage Accounting:		
Ending reservoir elevation .....	FT	4,405.00

**BASIN ELECTRIC POWER COOPERATIVE—LARAMIE RIVER STATION WATER SOURCES AND STATION USEAGE MONTHLY  
REPORT—Continued**

Reservoir evaporation .....	AF	838.53
Evap. loss for temporary storage .....	AF	2.98
Trans. water to temporary storage .....	AF	55.42
Direct diversion to perm. storage .....	AF	14,877.44
Direct diversion to flood storage .....	AF	16,115.09
Ending physical storage .....	AF	107,690.00
Total required releases .....	AF	11,901.00
<b>MAY 1995</b>		
<b>Grayrocks Inflows:</b>		
Boughton water at Bosler .....	AF	0
Conveyance loss Bosler to Grayrocks .....	AF	0
Laramie River above Grayrocks .....	AF	32,796.18
Boughton water at Grayrocks .....	AF	0
Inundated water rights .....	AF	407.05
Natural flow above Grayrocks .....	AF	32,389.13
Senior downstream rights .....	AF	0
Water available to Grayrocks .....	AF	32,389.13
<b>Grayrocks Downstream Release:</b>		
Laramie River below Grayrocks .....	AF	10,549.64
Laramie River at Ft. Laramie .....	AF	10,253.11
Bypass for senior rights .....	AF	0
Releases charged against storage .....	AF	10,549.66
Water for storage or diversion .....	AF	32,389.13
Flood storage releases .....	AF	0
Physical spill .....	AF	0
<b>LRS Water Usage:</b>		
Inundated water to LRS .....	AF	310.13
Inundated water to temporary storage .....	AF	96.90
Boughton water to LRS .....	AF	0
Boughton water to temporary storage .....	AF	0
Direct diversion to LRS .....	AF	821.88
Temporary storage to LRS .....	AF	0
Permanent storage to LRS .....	AF	0
Red Well water to LRS .....	AF	0.01
Green Well water to LRS .....	AF	0.03
Total water to LRS .....	AF	1,132.05
<b>Grayrocks Reservoir Storage Accounting:</b>		
Ending reservoir elevation .....	FT	4,400.60
Reservoir evaporation .....	AF	11.92
Evap. loss for temporary storage .....	AF	0.04
Trans. water to temporary storage .....	AF	96.90
Direct diversion to perm. storage .....	AF	21,067.79
Direct diversion to flood storage .....	AF	0
Ending physical storage .....	AF	92,443.00
Total required releases .....	AF	10,251.34
<b>APRIL 1995</b>		
<b>Grayrocks Inflows:</b>		
Boughton water at Bosler .....	AF	0
Conveyance loss Bosler to Grayrocks .....	AF	0
Laramie River above Grayrocks .....	AF	3,170.62
Boughton water at Grayrocks .....	AF	0
Inundated water rights .....	AF	0
Natural flow above Grayrocks .....	AF	3,170.62
Senior downstream rights .....	AF	0
Water available to Grayrocks .....	AF	3,170.62
<b>Grayrocks Downstream Release:</b>		
Laramie River below Grayrocks .....	AF	3,431.85
Laramie River at Ft. Laramie .....	AF	3,093.27
Bypass for senior rights .....	AF	0
Releases charged against storage .....	AF	3,322.94
Water for storage or diversion .....	AF	3,170.62
Flood storage releases .....	AF	0
Physical spill .....	AF	108.89
<b>LRS Water Usage:</b>		
Inundated water to LRS .....	AF	0
Inundated water to temporary storage .....	AF	0

**BASIN ELECTRIC POWER COOPERATIVE—LARAMIE RIVER STATION WATER SOURCES AND STATION USEAGE MONTHLY  
REPORT—Continued**

Boughton water to LRS .....	AF	0
Boughton water to temporary storage .....	AF	0
Direct diversion to LRS .....	AF	1,605.72
Temporary storage to LRS .....	AF	0
Permanent storage to LRS .....	AF	0
Red Well water to LRS .....	AF	0.24
Green Well water to LRS .....	AF	0.06
<b>Total water to LRS .....</b>	<b>AF</b>	<b>1,606.02</b>
<b>Grayrocks Reservoir Storage Accounting:</b>		
Ending reservoir elevation .....	FT	4,394.30
Reservoir evaporation .....	AF	719.17
Evap. loss for temporary storage .....	AF	2.40
Trans. water to temporary storage .....	AF	0
Direct diversion to perm. storage .....	AF	127.10
Direct diversion to flood storage .....	AF	0
Ending physical storage .....	AF	72,786
<b>Total required releases .....</b>	<b>AF</b>	<b>2,975.25</b>
<b>MARCH 1995</b>		
<b>Grayrocks Inflows:</b>		
Boughton water at Bosler .....	AF	0
Conveyance loss Bosler to Grayrocks .....	AF	0
Laramie River above Grayrocks .....	AF	4,731.64
Boughton water at Grayrocks .....	AF	0
Inundated water rights .....	AF	0
Natural flow above Grayrocks .....	AF	4,731.64
Senior downstream rights .....	AF	0
Water available to Grayrocks .....	AF	4,731.64
<b>Grayrocks Downstream Release:</b>		
Laramie River below Grayrocks .....	AF	2,496.04
Laramie River at Ft. Laramie .....	AF	2,524.16
Bypass for senior rights .....	AF	0
Releases charged against storage .....	AF	2,496.05
Water for storage or diversion .....	AF	4,731.64
Flood storage releases .....	AF	0
Physical spill .....	AF	0
<b>LRS Water Useage:</b>		
Inundated water to LRS .....	AF	0
Inundated water to temporary storage .....	AF	0
Boughton water to LRS .....	AF	0
Boughton water to temporary storage .....	AF	0
Direct diversion to LRS .....	AF	1,317.40
Temporary storage to LRS .....	AF	0
Permanent storage to LRS .....	AF	0
Red Well water to LRS .....	AF	0.03
Green Well water to LRS .....	AF	0.41
<b>Total water to LRS .....</b>	<b>AF</b>	<b>1,317.84</b>
<b>Grayrocks Reservoir Storage Accounting:</b>		
Ending reservoir elevation .....	FT	4,395
Reservoir evaporation .....	AF	907.91
Evap. loss for temporary storage .....	AF	3.01
Trans. water to temporary storage .....	AF	0
Direct diversion to perm. storage .....	AF	1,021.79
Direct diversion to flood storage .....	AF	0
Ending physical storage .....	AF	74,840
<b>Total required releases .....</b>	<b>AF</b>	<b>2,459.54</b>
<b>FEBRUARY 1995</b>		
<b>Grayrocks Inflows:</b>		
Boughton water at Bosler .....	AF	0
Conveyance loss Bosler to Grayrocks .....	AF	0
Laramie River above Grayrocks .....	AF	5,208.67
Boughton water at Grayrocks .....	AF	0
Inundated water rights .....	AF	0
Natural flow above Grayrocks .....	AF	5,208.67
Senior downstream rights .....	AF	0

**BASIN ELECTRIC POWER COOPERATIVE—LARAMIE RIVER STATION WATER SOURCES AND STATION USEAGE MONTHLY  
REPORT—Continued**

Water available to Grayrocks .....	AF	5,208.67
Grayrocks Downstream Release:		
Laramie River below Grayrocks .....	AF	2,282.41
Laramie River at Ft. Laramie .....	AF	2,428.00
Bypass for senior rights .....	AF	0
Releases charged against storage .....	AF	2,282.38
Water for storage or diversion .....	AF	5,208.67
Flood storage releases .....	AF	0
Physical spill .....	AF	0
LRS Water Usage:		
Inundated water to LRS .....	AF	0
Inundated water to temporary storage .....	AF	0
Boughton water to LRS .....	AF	0
Boughton water to temporary storage .....	AF	0
Direct diversion to LRS .....	AF	1,222.94
Temporary storage to LRS .....	AF	0
Permanent storage to LRS .....	AF	0
Red Well water to LRS .....	AF	0
Green Well water to LRS .....	AF	0
Total water to LRS .....	AF	1,222.94
Grayrocks Reservoir Storage Accounting:		
Ending reservoir elevation .....	FT	4,394.8
Reservoir evaporation .....	AF	0
Evap. loss for temporary storage .....	AF	0
Trans. water to temporary storage .....	AF	0
Direct diversion to perm. storage .....	AF	1,742.04
Direct diversion to flood storage .....	AF	0
Ending physical storage .....	AF	74,253
Total required releases .....	AF	2,221.52
JANUARY 1995		
Grayrocks Inflows:		
Boughton water at Bosler .....	AF	0
Conveyance loss Bosler to Grayrocks .....	AF	0
Laramie River above Grayrocks .....	AF	5,163.05
Boughton water at Grayrocks .....	AF	0
Inundated water rights .....	AF	0
Natural flow above Grayrocks .....	AF	5,163.05
Senior downstream rights .....	AF	0
Water available to Grayrocks .....	AF	5,163.05
Grayrocks Downstream Release:		
Laramie River below Grayrocks .....	AF	2,618.82
Laramie River at Ft. Laramie .....	AF	2,752.70
Bypass for senior rights .....	AF	0
Releases charged against storage .....	AF	2,522.60
Water for storage or diversion .....	AF	5,163.05
Flood storage releases .....	AF	0
Physical spill .....	AF	96.20
LRS Water Usage:		
Inundated water to LRS .....	AF	0
Inundated water to temporary storage .....	AF	0
Boughton water to LRS .....	AF	0
Boughton water to temporary storage .....	AF	0
Direct diversion to LRS .....	AF	1,465.17
Temporary storage to LRS .....	AF	0
Permanent storage to LRS .....	AF	0
Red Well water to LRS .....	AF	0.49
Green Well water to LRS .....	AF	0.26
Total water to LRS .....	AF	1,465.92
Grayrocks Reservoir Storage Accounting:		
Ending reservoir elevation .....	FT	4,394.6
Reservoir evaporation .....	AF	0
Evap. loss for temporary storage .....	AF	0
Trans. water to temporary storage .....	AF	0
Direct diversion to perm. storage .....	AF	1,188.06
Direct diversion to flood storage .....	AF	0
Ending physical storage .....	AF	73,666

**BASIN ELECTRIC POWER COOPERATIVE—LARAMIE RIVER STATION WATER SOURCES AND STATION USEAGE MONTHLY  
REPORT—Continued**

Total required releases .....	AF	2,459.54
DECEMBER 1994		
Grayrocks Inflows:		
Boughton water at Bosler .....	AF	0
Conveyance loss Bosler to Grayrocks .....	AF	0
Laramie River above Grayrocks .....	AF	4,870.48
Boughton water at Grayrocks .....	AF	0
Inundated water rights .....	AF	0
Natural flow above Grayrocks .....	AF	4,870.48
Senior downstream rights .....	AF	0
Water available to Grayrocks .....	AF	4,870.48
Grayrocks Downstream Release:		
Laramie River below Grayrocks .....	AF	2,497.03
Laramie River at Ft. Laramie .....	AF	2,603.34
Bypass for senior rights .....	AF	0
Releases charged against storage .....	AF	2,496.96
Water for storage or diversion .....	AF	4,870.48
Flood storage releases .....	AF	0
Physical spill .....	AF	0
LRS Water Usage:		
Inundated water to LRS .....	AF	0
Inundated water to temporary storage .....	AF	0
Boughton water to LRS .....	AF	0
Boughton water to temporary storage .....	AF	0
Direct diversion to LRS .....	AF	1,628.62
Temporary storage to LRS .....	AF	0
Permanent storage to LRS .....	AF	0
Red well Water to LRS .....	AF	0.38
Green Well water to LRS .....	AF	0.26
Total water to LRS .....	AF	1,629.26
Grayrocks Reservoir Storage Accounting:		
Ending reservoir elevation .....	FT	4,394.3
Reservoir evaporation .....	AF	0
Evap. loss for temporary storage .....	AF	0
Trans. water to temporary storage .....	AF	0
Direct diversion to perm. storage .....	AF	827.95
Direct diversion to flood storage .....	AF	0
Ending physical storage .....	AF	72,786
Total required releases .....	AF	2,459.54
Grayrocks Inflows:		
Boughton water at Bosler .....	AF	0
Conveyance loss Bosler to Grayrocks .....	AF	0
Laramie River above Grayrocks .....	AF	3,661.54
Boughton water at Grayrocks .....	AF	0
Inundated water rights .....	AF	0
Natural flow above Grayrocks .....	AF	3,661.54
Senior downstream rights .....	AF	0
Water available to Grayrocks .....	AF	3,661.54
Grayrocks Downstream Release:		
Laramie River below Grayrocks .....	AF	2,475.61
Laramie River at Ft. Laramie .....	AF	2,665.63
Bypass for senior rights .....	AF	0
Releases charged against storage .....	AF	2,475.57
Water for storage or diversion .....	AF	3,661.54
Flood storage releases .....	AF	0
Physical spill .....	AF	0
LRS Water Usage:		
Inundated water to LRS .....	AF	0
Inundated water to temporary storage .....	AF	0
Boughton water to LRS .....	AF	0
Boughton water to temporary storage .....	AF	0
Direct diversion to LRS .....	AF	1,428.77
Temporary storage to LRS .....	AF	0
Permanent storage to LRS .....	AF	0
Red Well water to LRS .....	AF	0.44
Green Well water to LRS .....	AF	0.41

**BASIN ELECTRIC POWER COOPERATIVE—LARAMIE RIVER STATION WATER SOURCES AND STATION USEAGE MONTHLY  
REPORT—Continued**

Total water to LRS .....	AF	1,429.62
<b>Grayrocks Reservoir Storage Accounting:</b>		
Ending reservoir elevation .....	FT	4,394.2
Reservoir evaporation .....	AF	0
Evap. loss for temporary storage .....	AF	0
Trans. water to temporary storage .....	AF	0
Direct diversion to perm. storage .....	AF	150.65
Direct diversion to flood storage .....	AF	0
Ending physical storage .....	AF	72,493
Total required releases .....	AF	2,380.20
<b>Grayrocks Inflows:</b>		
Boughton water at Bosler .....	AF	0
Conveyance loss Bosler to Grayrocks .....	AF	0
Laramie River above Grayrocks .....	AF	2,851.88
Boughton water at Grayrocks .....	AF	0
Inundated water rights .....	AF	0
Natural flow above Grayrocks .....	AF	2,831.64
Senior downstream rights .....	AF	0
Water available to Grayrocks .....	AF	2,831.64
<b>Grayrocks Downstream Release:</b>		
Laramie River below Grayrocks .....	AF	2,499.41
Laramie River at Ft. Laramie .....	AF	3,062.13
Bypass for senior rights .....	AF	0
Releases charged against storage .....	AF	2,483.69
Water for storage or diversion .....	AF	2,831.64
Flood storage releases .....	AF	0
Physical spill .....	AF	0
<b>LRS Water Usage:</b>		
Inundated water to LRS .....	AF	0
Inundated water to temporary storage .....	AF	0
Boughton water to LRS .....	AF	0
Boughton water to temporary storage .....	AF	0
Direct diversion to LRS .....	AF	1,549.84
Temporary storage to LRS .....	AF	64.06
Permanent storage to LRS .....	AF	0
Red Well water to LRS .....	AF	0.17
Green Well water to LRS .....	AF	0.02
Total water to LRS .....	AF	1,614.09
<b>Grayrocks Reservoir Storage Accounting:</b>		
Ending reservoir elevation .....	FT	4,394.5
Reservoir evaporation .....	AF	621.06
Evap. loss for temporary storage .....	AF	2.13
Trans. water to temporary storage .....	AF	0
Direct diversion to perm. storage .....	AF	26.77
Direct diversion to flood storage .....	AF	0
Ending physical storage .....	AF	73,373
Total required releases .....	AF	2,459.54

[FR Doc. 96-4807 Filed 3-4-96; 8:45 am]  
BILLING CODE 3125-01-M

### COMMODITY FUTURES TRADING COMMISSION

**Application of the Chicago Mercantile  
Exchange for Designation as a  
Contract Market in Futures and  
Options on the Indice de Precios y  
Cotizaciones "IPC" (Index of Prices  
and Quotes) of the Bolsa Mexicana de  
Valores (Mexican Stock Exchange)**  
AGENCY: Commodity Futures Trading  
Commission.

**ACTION:** Notice of availability of the  
terms and conditions of proposed  
commodity futures and option  
contracts.

**SUMMARY:** The Chicago Mercantile  
Exchange (CME or Exchange) has  
applied for designation as a contract  
market in futures and futures options on  
the Indice de Precios y Cotizaciones  
"IPC" (Index of Prices and Quotes) of  
the Bolsa Mexicana de Valores (Mexican  
Stock Exchange). The Acting Director of  
the Division of Economic Analysis  
(Division) of the Commission, acting

pursuant to the authority delegated by  
Commission Regulation 140.96, has  
determined that publication of the  
proposals for comment is in the public  
interest, will assist the Commission in  
considering the views of interested  
persons, and is consistent with the  
purposes of the Commodity Exchange  
Act.

**DATES:** Comments must be received on  
or before April 4, 1996.



**ADDRESSES:** Interested persons should submit their views and comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, Three Lafayette Centre, 21st Street NW., Washington, DC 20581. Reference should be made to the CME IPC contracts.

**FOR FURTHER INFORMATION CONTACT:** Please contact Stephen Sherrod of the Division of Economic Analysis, Commodity Futures Trading Commission, Three Lafayette Centre, 21st Street, Washington, DC, 20581, telephone 202-418-5277.

**SUPPLEMENTARY INFORMATION:** Copies of the terms and conditions will be available for inspection at the Office of the Secretariat, Commodity Futures Trading Commission, Three Lafayette Centre, 21st Street Washington, D.C. 20581. Copies of the terms and conditions can be obtained through the Office of the Secretariat by mail at the above address or by phone at (202) 418-5097.

Other materials submitted by the CME in support of the applications for contract market designation may be available upon request pursuant to the Freedom of Information Act (5 U.S.C. 552) and the Commission's regulations thereunder (17 CFR Part 145 (1987)), except to the extent they are entitled to confidential treatment as set forth in 17 CFR 145.5 and 145.9. Requests for copies of such materials should be made to the FOI, Privacy and Sunshine Act Compliance Staff of the Office of the Secretariat at the Commission's headquarters in accordance with 17 CFR 145.7 and 145.8.

Any person interested in submitting written data, views, or arguments on the proposed terms and conditions, or with respect to other materials submitted by the CME, should send such comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, Three Lafayette Centre, 21st Street, NW., Washington, DC 20581 by the specified date.

Issued in Washington, DC, on February 28, 1996.

Blake Imel,

*Acting Director.*

[FR Doc. 96-5029 Filed 3-4-96; 8:45 am]

BILLING CODE 6351-01-P

## CONSUMER PRODUCT SAFETY COMMISSION

### Sunshine Act Meeting

**AGENCY:** U.S. Consumer Product Safety Commission; Washington, DC.

**TIME AND DATE:** Wednesday, March 6, 1996, 10:00 a.m.

**LOCATION:** Room 420, East West Towers, 4330 East West Highway, Bethesda, Maryland.

**STATUS:** Open to the Public.

#### MATTER TO BE CONSIDERED:

##### *Multiple Tube Mine & Shell Fireworks*

The staff will brief the Commission on a final rule addressing the tip-over of large multiple tube mine and shell fireworks devices.

For a recorded message containing the latest agenda information, call (301) 504-0709.

#### CONTACT PERSON FOR ADDITIONAL

**INFORMATION:** Sadye E. Dunn, Office of the Secretary, 4330 East West Highway, Bethesda, MD 20207 (301) 504-0800.

Dated: February 29, 1996.

Sadye E. Dunn,

*Secretary.*

[FR Doc. 96-5280 Filed 3-10-96; 3:20 pm]

BILLING CODE 6355-01-M

### Sunshine Act Meeting

**AGENCY:** U.S. Consumer Product Safety Commission; Washington, DC.

**DATE & TIME:** Thursday, March 7, 1996, 10:00 a.m.

**LOCATION:** Room 410, East West Towers, 4330 East West Highway, Bethesda, Maryland.

**STATUS:** Closed to the Public.

#### MATTER TO BE CONSIDERED:

##### *Compliance Status Report*

The staff will brief the Commission on the status of various compliance matters.

For a recorded message containing the latest agenda information, call (301) 504-0709.

#### CONTACT PERSON FOR ADDITIONAL

**INFORMATION:** Sadye E. Dunn, Office of the Secretary, 4330 East West Highway, Bethesda, MD 20207 (301) 504-0800.

Dated: February 29, 1996.

Sadye E. Dunn,

*Secretary.*

[FR Doc. 96-5281 Filed 3-1-96; 3:10 pm]

BILLING CODE 6355-01-M

## DEPARTMENT OF DEFENSE

### Department of the Air Force

**Acceptance of Group Application Under Pub. L. 95-202 and Department of Defense Directive (DODD) 1000.20; "U.S. Civilian Flight Crew and Aviation Ground Support Employees of Northeast Airlines Atlantic Division, Who Served Overseas as a Result of Northeast Airlines Contract With the Air Transport Command During the Period December 7, 1941 Through August 14, 1945"**

Under the provisions of Section 401, Public Law 95-202 and DoD Directive 1000.20, the Department of Defense Civilian/Military Service Review Board has accepted an application on behalf of the group known as: "U.S. Civilian Flight Crew and Aviation Ground Support Employees of Northeast Airlines Atlantic Division, who served Overseas as a result of Northeast Airlines Contract with the Air Transport Command During the Period December 7, 1941, through August 14, 1945." Persons with information or documentation pertinent to the determination of whether the service of this group should be considered active military service to the Armed Forces of the United States are encouraged to submit such information or documentation within 60 days to the DOD Civilian/Military Service Review Board, Secretary of the Air Force Personnel Council, 1535 Command Drive, EE-Wing, Third Floor, Andrews AFB, MD 20762-7002. Copies of documents or other materials submitted cannot be returned. For further information, contact Mr. Johnston, (301) 981-5329.

Patsy J. Conner,

*Air Force Federal Register Liaison Officer.*

[FR Doc. 96-5084 Filed 3-4-96; 8:45 am]

BILLING CODE 3910-01-M

### Defense Logistics Agency

#### Cooperative Agreement Revised Procedures

**AGENCY:** Defense Logistics Agency (DLA).

**ACTION:** Cooperative Agreements Proposed Revised Procedures.

**SUMMARY:** This proposed revised procedure implements Title 10, United States Code, Chapter 142, as amended, which authorizes the Secretary of Defense, acting through the Director, Defense Logistics Agency, to enter into cost sharing cooperative agreements to support procurement technical

assistance programs established by state and local governments, private nonprofit organizations, Tribal organizations, and Indian-owned economic enterprises. Subpart III of this issuance establishes the proposed administrative procedures to be implemented by DLA to enter into such agreements for this purpose.

**DATES:** Comments will be accepted until March 29, 1996. Proposed effective date: April 8, 1996.

**FOR FURTHER INFORMATION CONTACT:**

Mr. Sim Mitchell, Program Manager, Office of Small and Disadvantaged Business Utilization (DDAS), Defense Logistics Agency, 8725 John J. Kingsman Rd., Suite 2533, Fort Belvoir, VA 22060-6221, Telephone (703) 767-1650.

Sim C. Mitchell,

*Program Manager, Office of Small and Disadvantaged Business Utilization.*

## I. Background Information

The Procurement Technical Assistance Cooperative Agreement Program (PTACAP) was established by the Fiscal Year (FY) 1985 Department of Defense (DoD) Authorization Act, Public Law 98-525. The Public Law amended Title 10, United States Code (U.S.C.), by adding Chapter 142. Title 10, U.S.C., as amended, continues to authorize the Secretary of Defense, acting through the Director, Defense Logistics Agency (DLA), to enter into cost sharing cooperative agreements to support procurement technical assistance (PTA) programs established by eligible entities.

DoD's efforts to increase competition in the private sector have been supplemented by many state and local governments, and other entities that operate PTA programs. The DoD PTACAP provides assistance to eligible entities by sharing the cost of establishing new and/or maintaining existing PTA programs.

The enabling legislation placed the following limitation on the use of funds allocated to the program:

A. DoD's share of an eligible entity's net program cost shall not exceed 50%, unless the eligible entity proposes to cover a distressed area. If the eligible entity proposes to cover a distressed area, the DoD share may be increased to an amount not to exceed 75%. In no event shall DoD's share of net program cost exceed \$150,000 for programs providing less than statewide coverage or \$300,000 for programs providing statewide coverage.

B. For the American Indian program, DoD's share of net program cost shall not exceed 75% or \$150,000, whichever

is less, for programs providing services on reservations within one Bureau of Indian Affairs (BIA) service area. For programs providing services to 100% of the reservations located within one BIA service area and at least 50% of the reservations located within another BIA service area (multi-area coverage), DoD's share of net program cost shall not exceed 75% or \$300,000, whichever is less.

C. No funds available to DoD may be provided by grant or contract to any institution of higher education that has a policy of denying, or which effectively prevents, the Secretary of Defense from obtaining for military recruiting purposes—

1. entry to campuses or access to students (individuals who are 17 years of age or older) on campuses; or

2. access to directory information pertaining to students.

D. No funds appropriated or otherwise available to the Department of Defense may be obligated by contract or by grant (including a grant of funds to be available for student aid) to any institution of higher education that, as determined by the Secretary of Defense, has an anti-ROTC policy and at which, as determined by the Secretary, the Secretary would otherwise maintain or seek to establish a unit of the Senior Reserve Officer Training Corps or at which the Secretary would otherwise enroll or seek to enroll students for participation in a unit of the Senior Reserve Officer Training Corps at another nearby institution of higher education. The term "anti-ROTC policy" means a policy or practice of an institution of higher education that—

1. prohibits, or in effect prevents, the Secretary of Defense from maintaining or establishing a unit of the Senior Reserve Officer Training Corps at that institution, or

2. prohibits, or in effect prevents, a student at that institution from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

The purpose of the proposed revised procedure is to make available to all eligible entities the prerequisites, policies and procedures that will govern the award of cooperative agreements by DLA. Also, this procedure establishes the guidelines that will govern the administration of cooperative agreements.

Although this procedure will affect all eligible entities desiring to enter into a DLA awarded cooperative agreement, DLA has determined that this procedure does not involve a substantial issue of fact or law, and that it is unlikely to have a substantial or major impact on

the Nation's economy or large numbers of individuals or businesses. This determination is based on the fact that the proposed cooperative agreement procedure implements policies already published by the Office of Management and Budget (OMB) pursuant to Title 31, U.S.C., Chapter 63, Using Procurement Contracts and Grants and Cooperative Agreements. In addition, DLA cooperative agreements will be entered into pursuant to the authorities and restrictions contained in the annual DoD Authorization and Appropriation Acts. Therefore, public hearings were not conducted.

## II. Other Information

The language contained in the current cooperative agreement procedure limited the period of coverage to the FY 95 Program in that it addressed the FY 95 Authorization Act requirements in specific terms. This proposed revision to the procedure will provide general guidance for cooperative agreements entered into by the DLA and will become a permanent document for the duration of the FYs 96, 97 and 98 Programs.

Comments are invited on the procedure. Comments should be submitted to DLA, Office of Small and Disadvantaged Business Utilization, ATTN: DDAS, 8725 John J. Kingman Road, Suite 2533, Fort Belvoir, VA 22060-6221. Comments received after March 29, 1996 may not be considered in formulating revisions to the Procedure.

## III. Proposed Revision to DLA Procedure—Cooperative Agreements

### 3-1 Policy

A. Applications for cooperative agreements are obtained through the issuance of a DLA solicitation for cooperative agreement applications (hereafter referred to as a SCAA). The contents of this procedure shall be incorporated, in whole or in part, into the SCAA to establish administrative requirements to execute and administer DLA awarded cooperative agreements. The SCAA may include additional administrative requirements that are not included herein.

B. The SCAA is issued by the PTACAP Manager (hereafter referred to as Program Manager) of the DLA Office of Small and Disadvantaged Business Utilization every third fiscal year, i.e., FY 96, FY 99, etc. The Program Manager will respond to any SCAA questions that may arise.

C. Only one application will be accepted from a single eligible entity. An entity that submits more than one

application, or is listed as a subagreement applicant in another entity's application will not be considered for an award. D. Applications will not be accepted from applicants that apply as coequal partners or joint ventures. Only one organization can take the lead and primary responsibility for the proposed program. In other words, only one eligible entity can submit an application.

E. Applications will not be accepted from applicants who propose to provide less than county or equivalent (i.e., parish, borough) coverage. For example, if an applicant proposes to service any part of a county or equivalent, the applicant must service the entire county or equivalent.

F. Cooperative agreements will be awarded on a competitive basis consistent with the SCAA. It is DLA's policy to encourage fair and open competition when awarding cooperative agreements.

G. Letters of support and recommendation from Members of Congress are not necessary and will not be considered in the evaluation and selection of applications to receive cooperative agreement awards.

H. The SCAA shall be given the widest practical dissemination. It will be made available to all known eligible entities and to those that request copies after its issuance. All eligible entities interested in submitting an application under the SCAA will be invited to participate in a pre-application conference. Pre-application conferences will be held at the locations designated in the SCAA, approximately 30 calendar days prior to the SCAA's closing date.

I. The SCAA shall not be considered to be an offer made by DoD. It will not obligate DoD to make any awards under this Program.

J. In the event that insufficient funds are available to award all applicants that meet the minimum requirements, only those applicants found to be the most meritorious will be funded for an award.

K. If selected for an award, the applicant is bound to perform the services described in its application when the application is incorporated into the cooperative agreement award document.

L. DoD is not responsible for any monies expended or expenses incurred by applicants prior to the award of a cost sharing cooperative agreement. However, actual travel expenses incurred by FY 96 award recipients to participate in a FY 96 pre-application and/or postaward training conference may be reimbursed under the FY 96 cooperative agreement award subject to

the provisions of the applicable cost principles.

M. The award of a cooperative agreement under this Program shall not, in any way, obligate DoD to enter into a contract or give preference for the award of a contract to a business or firm which is or becomes a client of a DLA cooperative agreement recipient.

N. Cooperative agreement recipients must give special emphasis to assisting small disadvantaged business (SDB) firms and any historically black colleges and minority institutions that participate or aspire to participate in DoD prime and subcontracting opportunities. A concerted effort must be made by recipients to identify SDB firms and provide them with marketing and technical assistance, particularly where such firms are referred for assistance by a DoD component, other Federal agencies, and state and/or local governments.

O. Award recipients are not required to obtain or retain private, profit and/or nonprofit consultants to support the program. Any subcontract costs being proposed for consulting services shall not exceed 10% of total program cost for the general program or 25% of total program cost under the American Indian program. Applications containing subcontracting costs for consultant services in excess of 10% of total program cost for the general program and 25% of total program cost for the American Indian program, will be removed from consideration for an award.

P. Reasonable quantities of government publications, such as "Selling to the Military," may be furnished to award recipients at no cost, subject to availability. All requests for such publications must be submitted to the cognizant Deputy for Small Business.

Q. Each cooperative agreement recipient's area of performance will be limited to the county(ies) or equivalent specified in its cooperative agreement award. Recipients may voluntarily service clients outside their area of performance provided that the client's location is not being serviced by another PTA recipient. For the American Indian program, the recipient's area of performance will be limited to the reservation(s) specified in its cooperative agreement.

R. For the American Indian program, if a tribal organization is to perform services benefiting other Indian tribe(s), written approval must be obtained by the eligible entity from each Indian tribe it plans to service. Approval will consist of a written statement (signed by a responsible official authorized to legally

bind the Indian tribe it plans to service) indicating that the Indian tribe approves and agrees to accept the services to be provided by the tribal organization.

S. Cooperative agreement awards shall not be made to entities listed in the General Services Administration's (GSA) "Lists of Parties Excluded from Federal Procurement or Nonprocurement Programs." Cooperative agreements will not be awarded to entities who employ any person listed in GSA's "Lists of Parties Excluded from Federal Procurement or Nonprocurement Programs."

T. Applications submitted in response to the SCAA shall cover a 12, 24 or 36-month period. All other applications proposing different periods will not be considered for an award.

U. To be considered during the evaluation process, part-time PTA program employees must be employed by the PTA program a minimum of three calendar months per year for the base year and each of the option years. Time employed must be performed continuously or incrementally for each 12-month period.

V. Cooperative agreement recipients shall not purchase non-expendable tangible personal property with a delivery date later than 90 days prior to the expiration of the cooperative agreement's effective period. Cost of non-expendable tangible personal property delivered later than 90 days prior to the expiration of the cooperative agreement's effective period will be disallowed.

W. Cooperative agreement recipients will be authorized to use GSA's subscription schedules. Usage will be limited to subscription services only.

X. Cooperative agreement recipients are required to provide information to their clients relating to the objectives of the Government's Electronic Commerce/Electronic Data Interchange (EC/EDI) initiatives which are as follow:

1. Exchange procurement information such as solicitations, offers, contracts, purchase orders, invoices, payments, and other contractual documents electronically between the private sector and the Federal government to the maximum practicable extent;

2. Provide businesses, including small, small disadvantaged, and women-owned businesses with greater access to Federal procurement opportunities;

3. Ensure that potential suppliers are provided simplified access to the Federal government's electronic commerce system;

4. Employ nationally and internationally recognized data formats that serve to broaden and ease the

electronic inter- change of data. (These formats are the ANSI ASC X-12 and UNEDIFACT formats); and

5. Use agency and industry systems and networks to enable the Government and potential suppliers to exchange information and access Federal procurement data.

Y. The recipient may add funds to its program after all program funds are properly expended and before expiration of the cooperative agreement's effective period. In the event funds are added to the program, the reimbursable ratio will not be affected and the funds will not require allocation by object class category. However, total funds expended during the effective period must be reported on the DLA Form 1806, Procurement Technical Assistance Cooperative Agreement Performance Report. The expenditure of additional funds shall be made in accordance with the applicable cost principles.

Z. If the recipient charges or plans to charge a fee or service charge for PTA given to business firms/clients, or receives any other income as a result of operating the PTACAP, the amount of such reimbursement must be added to total program cost.

### 3-2 Scope

This procedure implements Title 10, U.S.C., Chapter 142, as amended, and establishes procedures and guidelines for the award and administration of cost sharing cooperative agreements entered into between DLA and eligible entities. Under these agreements, financial assistance provided by DoD to recipients will cover the DoD share of the cost of establishing new and/or maintaining existing PTA programs which furnish PTA to business entities.

### 3-3 Definitions

The following definitions apply for the purpose of this procedure.

A. Act. The enabling legislation that authorizes the establishment and continuation of the PTA Cooperative Agreement Program each fiscal year.

B. Administrative Grants Officer (AGO). A person with the authority to administer grants or cooperative agreements consistent with the authority delegated by the Grants Officer.

C. Agency. A field office, of one of the twelve service areas, as published by the Bureau of Indian Affairs (BIA), US Department of the Interior.

D. American National Standards Institute (ANSI) Standard. A document published by ANSI that has been approved through the consensus process of public announcement and review.

Each of these standards must have been developed by an ANSI committee and must be revisited by that committee within five years after approval for update.

E. Cash contributions. The recipient's cash outlay, including the outlay of money contributed to the recipient by third parties.

F. Civil jurisdiction. All cities with a population of at least 25,000 and all counties. Townships of 25,000 or more population are also considered as civil jurisdictions in four States (Michigan, New Jersey, New York, and Pennsylvania). In Connecticut, Massachusetts, Puerto Rico and Rhode Island where counties have very limited or no government functions, the classifications are done for individual towns.

G. Client. A recognized business entity, including a corporation, partnership, or sole proprietorship, organized for profit or nonprofit, which is small or other than small, that has the potential or is seeking to market its goods and/or services as a prime or subcontractor to DoD, other Federal agencies, state and/or local governments. For the American Indian program, the client must be located on a reservation.

H. Commercial Item.

1. Any item, other than real property, that is of a type customarily used for nongovernmental purposes and that—

a. has been sold, leased, or licensed to the general public; or  
b. Has been offered for sale, lease, or license to the general public;

2. Any item that evolved from an item described in paragraph 1. of this definition through advances in technology or performance and that is not yet available in the commercial marketplace, but will be available in the commercial marketplace in time to satisfy the delivery requirements under a Government solicitation;

3. Any item that would satisfy a criterion expressed in paragraph 1. or 2. of this definition, but for—

a. Modifications of a type customarily available in the commercial marketplace; or

b. Minor modifications of a type not customarily available in the commercial marketplace made to meet Federal Government requirements. "Minor" modifications means modifications that do not significantly alter the nongovernmental function or essential physical characteristics of an item or component, or change the purpose of a process. Factors to be considered in determining whether a modification is minor include the value and size of the modification and the comparative value

and size of the final product. Dollar values and percentages may be used as guideposts, but are not conclusive evidence that a modification is minor;

4. Any combination of items meeting the requirements of paragraph 1., 2., 3., or 5. of this definition that are of a type customarily combined and sold in combination to the general public;

5. Installation services, maintenance services, repair services, training services, and other services if such services are procured for support of an item referred to in paragraph 1., 2., 3., or 4. of this definition, and if the source of such services—

a. Offers such services to the general public and the Federal Government contemporaneously and under similar terms and conditions; and

b. Offers to use the same work force for providing the Federal Government with such services as the source uses for providing such services to the general public;

6. Services of a type offered and sold competitively in substantial quantities in the commercial marketplace based on established catalog or market prices for specific tasks performed under standard commercial terms and conditions. This does not include services that are sold based on hourly rates without an established catalog or market price for a specific service performed;

7. Any item, combination of items, or service referred to in paragraphs 1. through 6., notwithstanding the fact that the item, combination of items, or service is transferred between or among separate divisions, subsidiaries, or affiliates of a contractor; or

8. A nondevelopmental item, if the procuring agency determines the item was developed exclusively at private expense and sold in substantial quantities, on a competitive basis, to multiple State and local governments.

I. Consultant services. Marketing and technical assistance obtained from private nonprofit and/or profit making individuals, organizations or otherwise qualified business entities to augment the capabilities of the PTA center.

J. Cooperative agreement. A binding legal instrument reflecting a relationship between DLA and the recipient of a cooperative agreement when the principal purpose of the relationship is to transfer a thing of value to the recipient to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring property or services for the direct benefit or use of the US Government. Substantial involvement is expected between DLA and the recipient when

carrying out the activity contemplated in the agreement.

**K. Cooperative agreement**

Application. An applicant's response to the SCAA describing its planned PTA program.

**L. Cooperative agreement award recipient.** An organization receiving financial assistance directly from DLA to carry out a PTA program. Awards will only be made to legal entities recognized under the laws in the State in which the entity is organized.

**M. Cost matching or sharing.** The portion of project or program costs not borne by the Federal Government.

**N. Counseling session.** A documented counseling session (telephone call, correspondence or personal discussion) held with a business firm/client, where professional guidance is provided to assist the business firm/client in marketing its goods and/or services to DoD, other Federal agencies, and state and local governments. This includes, but is not limited to, providing advice and assistance such as:

1. assisting business firms by providing marketing and technical assistance in selling their goods and/or services to DoD, other Federal agencies, and state and local governments;

2. assisting with understanding specifications;

3. preparing applicants to be placed on solicitation mailing lists;

4. preparing offers;

5. providing postaward assistance in areas such as production, quality system requirements, finance, engineering, transportation and packaging; and

6. providing information to business firms/clients on the DoD Mentor-Protege Pilot Program; Defense Conversion, Reinvestment and Transition Assistance Act of 1992; The Metric Conversion Act; Electronic Commerce/Electronic Data Interchange (EC/EDI); and commercial item acquisitions. The distribution of publications, specifications, bid matches or simply referring business firms/clients to another source for advice or assistance is not a counseling session.

**O. Direct cost.** Any cost that can be identified specifically with a particular final cost objective. No final cost objective shall have allocated to it as a direct cost any cost, if other costs incurred for the same purpose, in like circumstances, have been included in any indirect cost pool to be allocated to that or any other final cost objective.

**P. Distressed area.** The geographical area to be serviced by an eligible entity in providing PTA to business firms physically located within an area that:

1. has a per capita income of 80% or less of that State's average;

2. has an unemployment rate that is one percent greater than the national average for the most recent 24-month period in which statistics are available; or

3. is a "reservation" which includes Indian reservations, public domain Indian allotments, former Indian reservations in Oklahoma, and land held by incorporated Native groups, regional corporations, and village corporations under the provisions of the Alaska Native Claims Settlement Act.

**Q. Duplicate coverage.** A situation caused by two or more applicants offering to provide marketing and technical assistance to clients located within the same county(ies) or equivalent within the same geographic area.

**R. Electronic Commerce (EC).** The end-to-end, paperless business environment that integrates electronic transfer and automated business systems. EC includes EDI, FAX, Bar Coding, Electronic Funds Transfer, etc.

**S. Electronic Commerce in Contracting (ECIC).** Refers to electronic procurement transactions.

**T. Electronic Data Interchange (EDI).** A subset of EC. EDI is the computer-to-computer exchange of routine business transactions.

**U. Eligible entities.** Organizations qualifying to submit an application as follows:

**1. General Program:**

- a. State government. Any of the several states of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State, exclusive of local governments. The term does not include any public and Indian housing agency under the US Housing Act of 1937.

- b. Local government. A county, municipality, city, town, township, local public authority (including any public and Indian Housing agency under the US Housing Act of 1937), school district, special district, intrastate district, council of governments (whether or not incorporated as a nonprofit corporation under State law), any other regional or interstate government entity (such as regional planning agencies), or any agency or instrumentality of a local government. The term does not include institutions of higher education and hospitals.

**c. Private, nonprofit organizations.**

- (1) A business entity organized and operated exclusively for charitable, scientific, or educational purposes, of which no part of the earnings inure to the benefit of any private shareholder or

individual, of which no substantial part of the activities is carrying on propaganda or otherwise attempting to influence legislation or participating in any political campaign on behalf of any candidate for public office, and which are exempt from Federal income taxation under section 501 of the Internal Revenue Code.

**(2) American Indian Program:**

**(a) Indian Economic enterprise.** Any Indian-owned (as defined by the Secretary of the Interior) commercial, industrial, or business activity established or organized, whether or not such economic enterprise is organized for profit or nonprofit purposes: Provided, That such Indian ownership shall constitute not less than 51 per centum of the enterprise.

**(b) Indian/Tribal Organization.** The recognized governing body of any Indian tribe; any legally established organization of Indians which is controlled, sanctioned, or chartered by such governing body, or which is democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of Indians in all phases of its activities: Provided, that in any case where a cooperative agreement is made to an organization to perform services benefitting more than one Indian tribe, the approval of each such Indian tribe shall be a prerequisite to the letting or making of such cooperative agreement.

**V. Existing program.** Any PTA program that had a cooperative agreement with DLA for one or more years.

**W. Federal funds authorized.** The total amount of Federal funds obligated by the Federal government for use by the recipient.

**X. Follow-up counseling session.** A counseling session held with a client subsequent to the initial counseling session.

**Y. Grants officer.** An official with the authority to enter into, administer, and/or terminate grants or cooperative agreements.

**Z. Indian.** Any person who is a member of any Indian tribe, band, group, pueblo, or community which is recognized by the Federal Government as eligible for services from the BIA and any "Native" as defined in the Alaska Native Claims Settlement Act [43 U.S.C. 1601 et seq.].

**AA. Indian tribe.** Any Indian tribe, band, group, pueblo, or community, including Native villages and Native groups (including corporations organized by Kenai, Sitka, and Kodiak) as defined in the Alaska Native Claims Settlement Act [43 USC Section 1601 et

seq.], which is recognized by the Federal Government as eligible for services from the Bureau of Indian Affairs.

AB. Indirect cost. Any cost not directly identified with a single final cost objective, but identified with two or more final cost objectives or an intermediate cost objective. An indirect cost is not subject to treatment as a direct cost.

AC. Initial counseling session. The first counseling session held by a recipient with a business firm. The initial counseling session may determine that the business firm has no potential to do business with a Federal agency and/or state and local government.

AD. In-kind contributions. The value of noncash contributions provided by the eligible entity and non-Federal parties to the PTA Program. Only when authorized by Federal legislation may property or services purchased with Federal funds be considered as in-kind contributions. In-kind contributions may be in the form of charges for real property and nonexpendable personal property and the value of goods and services directly benefiting and specifically identifiable to the project or program.

AE. Integrated automated information environment. Computer-to-computer exchange of public standard formatted messages through use of a VAN.

AF. Multi-area coverage. A PTA program that proposes to service 100% of the reservations located within one BIA service area and at least 50% of the reservations located within another BIA service area.

AG. Net program cost. The total program cost from all authorized sources- less any program income and/or other Federal funds not authorized to be shared.

AH. Networking. A method of providing assistance throughout the area to be serviced. Examples include:

1. locating assistance offices in area of industrial concentration;
2. establishing and/or maintaining data links with other organizations; and
3. creating data exchanges.

AI. New start. An eligible entity that is not an existing program.

AJ. Non-profit agencies representing the blind and severely disabled. A qualified nonprofit agency for the blind or the severely disabled which produces a commodity for, or provides a service to, the Government. For the PTACAP workshops may be treated as small businesses.

AK. Other Federal funds. Federal funds such as those provided by Federal agency(ies) other than the DoD PTA

Cooperative Agreement Program. When authorized by statute, Federal funds received from other sources, including grants, may be used as cost sharing and/or cost matching contributions.

AL. Outlays/expenditures. Charges made to the PTA program. They may be reported on a cash or accrual basis.

1. Cash basis. For reports prepared on a cash basis, outlays are the sum of:

- a. cash disbursements for direct charges for goods and services;
- b. the amount of indirect expense charged;
- c. the value of third party in-kind contributions applied; and
- d. the amount of cash advances and payments made to subrecipients.

2. Accrual basis. For reports prepared on an accrual basis, outlays are the sum of:

- a. cash disbursements for direct charges for goods and services;
- b. the amount of indirect expense incurred;
- c. the value of in-kind contributions applied;
- d. the net increase (or decrease) in the amounts owed by the recipient for goods and other property received, for services performed by employees, contractors, subrecipients and other payees; and
- e. other amounts becoming owed under programs for which no current services or performance are required.

AM. Per capita income. The estimated average amount per person of total money income received during the calendar year for all persons residing in a given political jurisdiction as published by the US Department of Commerce, Bureau of the Census.

AN. Prior approval. Written approval given by an authorized official evidencing prior consent as required by the cooperative agreement award document.

AO. Procurement Technical Assistance Cooperative Agreement Program (PTACAP). A program established to generate employment and improve the general economy of a locality by assisting business firms in obtaining and performing under DoD, other Federal agency and state and local government contracts.

AP. Program income. Gross income earned by the recipient or subrecipient from cooperative agreement supported activities. Program income includes fees for services performed, and the use or rental of personal property acquired with cooperative agreement funds. Except as otherwise provided in program regulations or the terms and conditions of the award, program income does not include the receipt of principal, interest or loans, rebates,

credits, discounts, refunds, etc., or interest earned on any of them.

AQ. Public Standard Format. A data exchange format which includes the ANSI format ASC X-12 and/or the United Nations Electronic Data Interchange for Administration, Commerce and Transport (UNEDIFACT).

AR. Reservation. Includes Indian reservations, public domain Indian allotments, former Indian reservations in Oklahoma, and land held by incorporated Native groups, regional corporations, and village corporations under the provisions of the Alaska Native Claims Settlement Act [43 U.S.C.A., Section 1601 et seq.].

AS. Service area. Any one of twelve area offices, as published by the US Department of the Interior, BIA, to include: Aberdeen, Albuquerque, Anardako, Billings, Eastern, Juneau, Minneapolis, Muskogee, Navajo, Phoenix, Portland and Sacramento.

AT. Small business (SB). As used in this solicitation, a business, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as SB under the criteria and size standards in 13 CFR 121.

AU. Small disadvantaged business (SDB). As used in this solicitation, a SB concern that is at least 51 percent unconditionally owned by one or more individuals who are both socially and economically disadvantaged, or a publicly owned business that has at least 51 percent of its stock unconditionally owned by one or more socially and economically disadvantaged individuals and that has its management and daily business controlled by one or more such individuals. This term also means a SB concern that is at least 51 percent unconditionally owned by an economically disadvantaged Indian tribe or Native Hawaiian organization, or publicly owned business that has at least 51 percent of its stock unconditionally owned by one of these entities, that has its management and daily business controlled by members of an economically disadvantaged Indian tribe or Native Hawaiian organization that meets the requirements of 13 CFR 124.

AV. Solicitation for cooperative agreement applications (SCAA). A document issued by DLA containing provisions and evaluation factors applicable to all applicants which apply for a PTA cooperative agreement.

AW. Statewide coverage. A PTA program which proposes to service at least 50% of a State's counties or

equivalent and 75% of the State's labor force.

AX. Subrecipient. The legal entity to which a written subagreement is awarded and which is accountable to the recipient of a cooperative agreement from DLA and any modification(s) thereto.

AY. Third party in-kind contributions. The value of non-cash contributions provided by non-Federal third parties. Third party in-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and the value of goods and services directly benefiting and specifically identifiable to the PTACAP.

AZ. Total program cost. All allowable costs as set forth in OMB Circular A-21, A-87 and A-122, as applicable.

A1. Total program outlays. All charges made to the PTA program. These charges include cash disbursements for direct charges for goods and services, the amount of indirect expense charged, the value of in-kind contributions applied, and the net increase (or decrease) in the amounts owed by the recipient for goods and other property received for services performed by employees, contractors and other payees, and other amounts becoming owed under programs for which no current services or performances are required.

A2. Unliquidated obligations. For financial reports prepared on a cash basis, means the amount of obligations incurred by the recipient that has not been paid. For reports prepared on an accrued expenditure basis, they represent the amount of obligations incurred by the recipient for which an outlay has not been recorded.

A3. Unobligated balance. The portion of the funds authorized by DLA that has not been obligated by the recipient which is determined by deducting the cumulative obligations from the cumulative funds authorized.

A4. Value added network (VAN). A commercial telecommunications service provider which passes electronic commerce traffic between a government entity and a commercial, private sector vendor.

A5. Woman-owned small business (WOB). A small business concern—(i) which is at least 51 per centum owned by one or more women; or in the case of a publicly owned business, at least 51 per centum of the stock of which is owned by one or more women; and (ii) whose management and daily business operations are controlled by one or more women.

### 3-4 Program Purpose and Requirements

A. The purpose of the PTACAP is to generate employment and to improve the general economy of a locality by assisting business firms in obtaining and performing under Federal, state and local government contracts.

B. Each PTA center must meet these minimum requirements set forth below. Failure to meet any of these requirements will be cause to deny or terminate an award.

#### 1. Service Area

Analyze the service area to identify its geographic and demographic characteristics. The applicant must maintain and provide information regarding the characteristics of the local economy (distressed or nondistressed) and the type of business firms located in the service area (SB, WOB, SDB, OTSB). Information must include:

a. An explanation how the business community will be made aware of the PTA Program; the types of assistance being offered to clients; what is required from a business firm to become a PTA center's client; and the impact the PTA center will have in generating employment within the service area.

b. The total number of counties or equivalent within the State and the identification of each county the applicant plans to service.

c. The average unemployment level for each county the applicant plans to service.

d. The average per capita income of the State and each county the applicant plans to service.

e. The total number of procurement outreach conferences the applicant plans to sponsor.

f. The total number of procurement outreach conferences the applicant plans to participate in other than as a sponsor.

g. The state's total population and the percent of the population that the applicant plans to service.

h. The total number of SB, WOB, SDB, and OTSB the applicant plans to service.

#### 2. Counseling and Client Information

Applicants must provide clients with counseling and information regarding marketing their goods and services to DoD, other Federal agencies, and state and local governments. The applicant shall:

a. Analyze the types of business firms within their geographic area to determine the types to be counseled (by product or service offered).

b. Shall maintain regulations and publications (or identify sources for

obtaining) that govern Federal, state and local government procurement, as applicable.

c. Identify marketing opportunities for clients consistent with their products and services.

d. Assist and advise clients concerning post award functions.

e. Educate clients in the following areas:

(1) DoD Mentor-Protege Pilot Program.

(2) Defense Conversion, Reinvestment and Transition Assistance Act of 1992.

(3) The Metric Conversion Act.

(4) The requirements and procedures used by DoD and other Federal agencies in the acquisition of commercial products.

f. Maintain records to document services provided during all counseling sessions (initial and follow-up) to include preparation of bidders mailing list applications.

#### 3. Electronic Commerce/Electronic Data Interchange

(EC/EDI)—Applicant must provide its clients with information pertaining to Electronic Commerce in Contracting (ECIC), including the routine computer exchange of procurement information such as solicitations, offers, contracts, purchase orders, invoices, payments, and other contractual documents electronically exchanged between the private sector and the Federal Government, to the maximum extent practicable, using ANSI ASC X-12 standards. Information to be provided to the client should include:

a. An explanation of how the business community will benefit from using EC/EDI.

b. A complete understanding of the Federal Government EC/EDI program to include:

(1) An identification and explanation of the functions of the various components of EC/EDI, such as Value Added network (VANs) and Value Added Services (VASS), Government gateways and networks, translation software, necessary hardware, and the Central Contractor Registration (CCR) system.

(2) An explanation of current OSD and Federal policies regarding ECIC.

(3) An explanation of transaction sets and implementation conventions.

(4) An explanation of the impact and applicability of the Internet on ECIC, including identification of Government home pages, electronic catalogs, electronic bulletin boards and other relevant net sites.

(5) Explanation of FACNET requirements and DoD and Federal efforts (and status) on meeting these requirements.



#### 4. Postaward Assistance

Applicant must assist, as appropriate, their clients with understanding Federal, state and local government requirements applicable to contracting for services, manufacturing, construction or other markets. As a minimum, the assistance should include but is not limited to:

- a. Production
- b. Quality System
- c. Accounting system requirements, and contract payments
- d. Transportation
- e. Packaging
- f. Subcontracting
- g. Property

#### 5. Performance Reporting

The PTA center shall collect sufficient information from its clients to supplement information maintained in its files to report current, complete and accurate information required by the Procurement Technical Assistance Cooperative Agreement Performance Report (DLA Form 1806). The DLA Form 1806 shall be submitted to the cognizant contract administration activity on a semiannual basis. The PTA center shall:

a. Segregate data by origin of award (DoD, other Federal agency, state and local government) and type of business (small and other than small) and socioeconomic status of the business receiving the award (SB, SDB, WOB, OTSB).

b. Have on file:

(1) A minimum of five success stories attesting to the PTA provided to DoD clients during the base and each option year. Each success story must be verified by a letter from the applicant's client stating that the story is true and has resulted from the direct and exclusive effort on behalf of the client by the PTA center.

(2) The number and dollar value of prime and subcontract awards received.

(3) A means of validating the number and dollar value for prime and subcontract awards received.

(4) A signed statement from the client confirming that the reported prime and/or subcontract awards were obtained as a result of the assistance provided by the PTA center.

(5) When requested by the reviewing activity, obtain detailed information such as: the contract awarding activity; name and telephone number of the point of contact at the contract awarding activity; and the contract number and dollar value of prime and/or subcontract awards from the client to support the information reported on the DLA Form 1806, when the information is not available in the PTA center's files.

c. Have on file for the PTA center the number of jobs generated and/or retain for the base and each option year resulting from the assistance provided by the PTA center.

#### 6. Client Satisfaction

Clients serviced by the award recipient shall be surveyed annually, as a minimum, to document client satisfaction with the assistance provided by the PTA center. The client shall be requested to assess the performance of the PTA center and its personnel in terms of:

- a. Timeliness and responsiveness to general and specific client needs;
- b. Flexibility and ability to change with evolving client circumstances;
- c. Commitment to the client's stated goals;
- d. Training offered and received, as appropriate; and,
- e. Overall capability to provide relevant advice and assistance to the client.

Clients shall rate the PTA center as satisfactory or unsatisfactory. The file will reflect, in sufficient detail, the PTA center's efforts to overcome areas of client dissatisfaction. The above information will be compiled, documented and maintained as a part of each client's permanent file, and as a collective report for the entire PTA center. The client rating information shall be made available to the Grants Officer or designated representative for review upon request.

C. The recipient and subrecipient(s) shall operate their PTA centers on a forty (40) hour week basis, or during the normal business hours of the state or local government or PTA center's parent organization throughout the effective period of the cooperative agreement. Vacation benefits and holidays allowed to the staff of the recipient and subrecipient(s) shall conform to the policy of the state or local government or PTA center's parent organization.

#### 3-5 Procedures

A. The SCAA and selection criteria are developed and prepared by the Headquarters (HQ), DLA PTA Cooperative Agreement Program Manager (hereafter referred to as Program Manager). The SCAA and selection criteria are approved by the HQ DLA PTA Cooperative Agreement Program Policy Committee (hereafter referred to as Policy Committee). The Policy Committee is comprised of representatives from HQ DLA. The Director, office of Small and Disadvantaged Business utilization, serves as the Policy Committee Chairman.

B. The Policy Committee is the final administrative appeal authority for disputes and protests.

C. Grants Officer (GO) as used herein refers to the GO assigned to HQ DLA Office of Small and Disadvantaged Business Utilization.

D. Applications and revisions received after the deadline for receipt of applications, as specified in the SCAA, will not be evaluated unless acceptable evidence is provided by the applicant. Acceptable evidence to support an otherwise late application or revision received after the closing time and date shall consist of:

1. An original U.S. Post Office receipt for registered or certified mail showing the date of mailing not later than five calendar days before the date specified for receipt of applications and revisions; or

2. When sent by U.S. Postal Service Express Mail Next Day Service—Post Office to Addressee, the date entered by the Post Office receiving clerk on the "Express Mail Next Day Service—Post Office to Addressee" label and the postmark on the envelope or wrapper and on the original receipt from the US Postal Service. The postmark date must be two working days prior to the date specified for receipt of applications. The term working days excludes weekends and Federal holidays. Applicants should request the postal clerk to place a legible hand cancellation "bull's-eye" postmark on both the receipt and envelope or wrapper.

3. If the application or revision is hand delivered, the specific time and delivery date shall be supported by a receipt given by the GO or designated representative.

E. The evaluation of applications and selection of award recipients resulting from responses to the SCAA shall be conducted as detailed below:

1. The GO will evaluate each application received to determine if the application: (i) offers at least a county or equivalent coverage; (ii) contains sufficient management, technical, cost, and other required information; (iii) has been signed by a responsible official authorized to bind the eligible entity; and (iv) otherwise meets the requirements of the SCAA. Applications that fail to meet the requirements of the SCAA will be removed from further consideration for an award by the GO and the applicant will be promptly notified of the reason for removal. The applicant's application will be retained with any other unsuccessful application(s) by the GO.

2. Program status classification. The GO will review and verify the accuracy of the applicant's program status stated



in item 8, "Type of Application" of the Standard Form (SF) 424. If the GO considers the program status misclassified, the matter will be reviewed with the applicant. If the applicant and the GO cannot agree, the GO will determine the applicant's program status based upon the information contained in the application at the time the solicitation closed. The GO's decision regarding the program's status is final.

3. Minor informalities and mistakes. The GO shall provide an applicant the opportunity to cure any deficiency resulting from a minor informality or irregularity contained in the offer or waive the deficiency, whichever is to the advantage of the Government. A minor informality or irregularity is one that is merely a matter of form and not of substance. It also pertains to some immaterial defect in an offer or variation of an offer from the exact requirements of the solicitation that can be corrected or waived without being prejudicial to other applicants. The defect or variation is immaterial when the effect on program quality is negligible when contrasted with the program's total cost. Two examples of minor informalities include the failure of the applicant to: (i) return the required number of copies of its application; and (ii) execute the certifications required by the SCAA clauses.

a. In cases of apparent mistakes and in cases where the GO has reason to believe that a mistake may have been made, the GO shall request verification from the applicant that the offer "should read as stated" calling attention to the suspected mistake. Any clerical mistake apparent in the offer may be corrected by the GO. Examples of apparent mistakes are: (i) obvious misplacement of a decimal point; (ii) incorrect transposition of numbers; and (iii) obvious mistake in identifying the program status (existing versus new start program). The GO shall obtain from the applicant a written verification of the offer intended.

b. Correction of a mistake by the GO shall be effected by attaching the verification to the original offer. The GO shall not make corrections on the application. Corrections shall be restated in the cooperative agreement award document, if the applicant receives an award.

c. If an applicant request permission to correct a mistake, and clear and convincing evidence establishes the existence of the mistake, the GO may make a determination permitting the applicant to correct the mistake. The determination to allow correction of mistakes will be made provided that

both the existence of the mistake and the application actually intended are established by clear and convincing evidence from the solicitation and application.

4. Notification of application removal from consideration for an award. The GO will notify the applicant by certified mail (return receipt requested) if its application is removed from further consideration for an award.

5. Duplicate coverage. An application shall not duplicate more than 25%, on an individual or cumulative basis, any of the counties or equivalent (for the general program) or any of the reservations (for the Indian program) proposed by other applicants. When the GO determines that two or more applicants are proposing to provide duplicate coverage in excess of 25%, selection priority will be given to the applicant that is determined to be best qualified by the evaluation team. Only one statewide program (under the general program) will be awarded in a state.

6. Each application will be reviewed by an evaluation team consisting of two procurement functionals, one technical functional, and one small business functional. Each evaluation factor will receive individual adjectival ratings (highly acceptable, acceptable, marginally acceptable, and unacceptable) based on the merit of the applicant's support for the particular evaluation element. The team will then collectively assess the overall application, taking into consideration the strengths and weaknesses of the application as it relates to each individual evaluation factor. A single adjectival rating will be assigned to the application which will be used to determine final award status. Applicants should be aware that ultimate award and inclusion into the DLA PTACAP may depend on funding limitations and constraints placed upon the Agency.

7. Award. The award recommendations are approved by the Program Manager and executed by the GO.

### 3-6 Evaluation Plan

#### A. Selection Procedures

1. This section outlines the procedures the Government will use during the selection process for the FY 96 PTACAP. The Government contemplates that multiple awards will be made from the applications submitted for the PTACAP. The Government at its discretion may select multiple applicants to perform PTACAP requirements at statewide and other

than statewide coverage levels provided that any individual application shall not duplicate any counties or equivalent (general program), or reservations (Indian program), proposed by other applicants.

2. The section entitled Evaluation Criteria describes the criteria the Government will use to select those applicants that provide the best overall value to satisfy PTACAP requirements. Evaluation criteria (in order of importance) are:

- a. Past Performance (Existing Programs Only);
- b. Management;
- c. Technical Qualifications;
- d. Service Area (geographic and demographic characteristics); and
- e. Cost Realism.

3. Information provided regarding past performance will be evaluated by the Government to determine the applicant's ability to perform PTACAP requirements. Applicants selected for the basic award will be considered for award of option(s) if their demonstrated performance is equal or better than that required by the base year or first option year cooperative agreement award and a satisfactory or better performance rating is received from the cognizant contract administration activity. In the absence of acceptable performance by the original awardee, other applicants may be selected to complete the option period(s).

4. Although cost realism is of lesser importance, the importance of cost realism could increase among applicants that are rated equally or nearly equal. Should applicants become equal or nearly equal in terms of the factors shown above, other factors listed below may be used as discriminating elements for determining the selection of applications among otherwise substantially equal applicants. These factors in descending order of importance are:

- a. Duplication of effort;
- b. Demographic make-up, to include population, unemployment, and labor surplus area coverage;
- c. Alternative methods employed to stimulate outreach efforts aimed at small disadvantaged businesses; and,
- d. Other strengths and weaknesses of note demonstrated in the application.

5. The recommendation of applicants to participate in the PTACAP will be made by the Evaluation Team based on an integrated assessment of all applications submitted in response to the solicitation and other terms and conditions agreed upon prior to award. The integrated assessment will involve a determination by the Government of the overall value of each proposal

judged in terms of the applicant's capability. Throughout the evaluation process, the Government will independently identify deficiencies within the applications. The team will collectively assess the overall application, taking into account the strengths and weaknesses of the application as it relates to each individual evaluation factor. A single adjectival rating will be assigned to the application, which will be used to determine final award status.

## B. Evaluation Criteria

### 1. Past Performance (Existing Programs Only)

a. The Government will evaluate the quality of the applicant's past performance. The assessment of the past performance will be used in two (2) ways:

(1) First, the assessment of the offeror's performance will be used as one means of evaluating the credibility of the applicant's application. A record of marginal or unacceptable past performance may be considered an indication that the representations made by the applicant are less than reliable. Such an indication may be reflected in the overall assessment of the applicant's application.

(2) Second, the assessment of the applicant's past performance will be used as one means of evaluating the relative capability of the applicant and the other applicants to meet the performance requirements of the PTACAP. Thus, an applicant with an exceptional record of past performance may receive a more favorable evaluation than another whose record is acceptable, even though both may have otherwise equally acceptable applications.

b. In investigating an applicant's past performance, the Government will consider the information in the applicant's proposal and information obtained from other sources, such as past and present clients, other Government agencies, and others who may have useful information.

c. Evaluation of past performance will be a subjective assessment based on a consideration of all relevant facts and circumstances. It will not be based on absolute standards of acceptable performance. The Government is seeking to determine whether the offeror has consistently demonstrated a commitment to client satisfaction and timely delivery of quality service at reasonable costs. This is a matter of judgement. Applicants may be given an opportunity to address especially unfavorable reports of past performance,

and the applicant's response or lack thereof will be taken into consideration.

d. By past performance, the Government means the applicant's record of conforming to the PTACAP requirements, including the administrative aspects of performance, reputation for reasonable and cooperative behavior, commitment to client satisfaction, and generally, the applicant's businesslike concern for the interests of the client.

### 2. Management

a. The proposed management team will be rated to determine the degree of experience offered by the team proposed and the likelihood of successful management under the PTACAP.

b. Management will be evaluated to determine whether it meets the PTACAP requirements.

c. The application will be evaluated to determine the financial strength and soundness of the organization. The availability of resources under the application will also be assessed. The strength of the plan will be assessed to determine the adequacy of the plan proposed.

### 3. Technical Qualifications

Understanding of and ability to meet PTACAP requirements by the personnel involved for this factor will be evaluated to determine the extent to which it meets the program requirements and the likelihood of success of the PTACAP as it relates to these requirements. Benefits will be evaluated in terms of management substance and achievability.

### 4. Service Area (Geographic and Demographic Characteristics)

a. The service area will be evaluated based upon the population to be serviced as well as the unemployment conditions in the area to determine the scope and nature of the coverage proposed.

b. Demographic characteristics will be evaluated including the total population of the state and the percentage of the population to be served and the unemployment conditions in the area. The unemployment rate for the most recent 24 month period for which statistics are available will be used in this process.

c. Service area will be evaluated to assess the extent to which the program maximizes coverage and achieves PTACAP requirements and objectives.

### 5. Cost Realism

Cost realism will be evaluated on the basis of the applicant's ability to project cost which indicates an understanding

of the nature and scope of the work required. The costs proposed will also be evaluated for reasonableness. Reasonableness is a judgement of the proposed program costs as compared to expected needs of the PTACAP, appropriate indices and other relevant measures. Implicit in the assessment is the need to establish that any application considered for an award must also be realistic with respect to the relationship of the cost to the level of performance proposed. This determination is critical to determining the offeror's understanding of the PTACAP requirements and probability of successful performance. Upon a determination of cost realism, a comparison of proposed costs will be made to the other evaluation factors and the Evaluation Team will make a decision as to which applications represent the best value to the Government. It is to be noted that this assessment will be a subjective judgement as to the relative value of the applications received. The Government reserves the right to verify any and all aspects of each applicant's application.

### 3-7 Evaluation Factors

Applications will be evaluated for merit and compliance with the PTACAP's solicitation requirements. In order to provide full consideration of the applicant's qualification for an award, each applicant should ensure that the information furnished is factual current, accurate, and complete. The content should be presented in a manner that will allow evaluators to determine the applicant's understanding of the SCAA, the operating environment desired in PTA centers, and how the applicant's overall concept meets requirements of the SCAA. Failure to provide the information requested may result in a determination that the application is unacceptable and will be removed from further consideration for an award. The Government reserves the right to verify information provided by the applicant for evaluation purposes and to request additional supporting information, if needed. The evaluation factors (in their order of importance) are:

A. Past Performance (Existing Programs Only). Applicants having no record of past performance under a DLA PTACAP will receive a neutral rating for this evaluation factor. A neutral rating for new programs will have no adverse effect on the determination for award. Each applicant will be evaluated on its most recent 12-month performance period (prior to 1 April 1996) under the existing solicitation regarding compliance with requirements;

management of the program; and, ability to account for and document associated costs. The applicant must summarize the requirements in its most recent 12-month performance period and describe how its program satisfied those requirements to include jobs generated and/or retained and justification for any funds that were or will be deobligated. Evaluation of past performance will be a subjective assessment based on a consideration of all relevant facts and circumstances. The most recent copy of the cognizant contract administration activity's evaluation report must be provided. The following criteria will be used to evaluate the application:

1. Highly acceptable—The application must demonstrate a high degree of success in satisfying all PTA Program requirements during the most recent 12-month performance period. The cognizant administration activity's evaluation report must substantiate that the applicant has an above average program.

2. Acceptable—The application must demonstrate that the applicant has met all PTA Program requirements during the most recent 12-month performance period. The cognizant administration activity's evaluation report must substantiate that the applicant has an adequate program.

3. Marginally acceptable—The application must demonstrate that the applicant has satisfied most of the PTA Program requirements during the most recent 12-month performance period. The cognizant administration activity's evaluation report must substantiate that the applicant has implemented most program requirements.

4. Unacceptable—The applicant has fulfilled few of the PTA Program requirements during the most current 12-month performance period. The cognizant administration activity's evaluation report must substantiate that the applicant has an inadequate program.

Note: Limit this discussion to 4 single-spaced, type-written pages.

#### B. Management

Each applicant will be evaluated on its management approach to successfully implement the PTA Program. The applicant shall describe the methods and procedures it plans to employ to manage the PTA Program in an efficient and effective manner. The applicant's approach will be rated to determine the degree of experience offered and the likelihood of successful management under the concept proposed. In addition, the evaluation will include an assessment of the overall strength and soundness of the

organization. The following criteria will be used to evaluate the application:

1. Highly acceptable—The applicant has fully demonstrated that the techniques and methodology it intends to employ will enable it to exceed all PTA Program requirements during the period of performance.

2. Acceptable—The applicant has demonstrated that the techniques and methodology it intends to employ are adequate and that its management approach will enable it to satisfy all PTA Program requirements.

3. Marginally acceptable—The applicant has minimally demonstrated that the management techniques and methodology it intends to employ will satisfy most of the PTA Program requirements.

4. Unacceptable—The applicant has not demonstrated an adequate understanding of the management techniques and methodology needed to successfully operate a PTA Program and satisfy requirements.

Note: Limit this discussion to 3 single-spaced, type-written pages.

#### C. Technical Qualifications

Each applicant will be evaluated on the qualifications of its personnel regarding the number of years of procurement experience, including government and industry experience, procurement related training, and education. The applicant must describe how its personnel fulfills these requirements. The following criteria will be used to evaluate the application:

1. Highly acceptable—The majority of the applicant's professional personnel have at least four years of acquisition experience; a baccalaureate degree, preferably in business related subject; and, have experience in operating a PTA Center or equivalent type organization.

2. Acceptable—The majority of the applicant's professional personnel have at least two years of acquisition experience; a baccalaureate degree, preferably in business related subject; and, have experience in operating a PTA Center or equivalent type organization.

3. Marginally acceptable—The majority of the applicant's professional personnel do not have more than one year of acquisition experience; have a baccalaureate degree, preferably in business related subject; and, have at least some experience in operating a PTA Center or equivalent type organization.

4. Unacceptable—The majority of the applicant's professional personnel do not have at least one year of acquisition experience; do not have a baccalaureate degree; and, have no experience in

operating a PTA Center or equivalent type organization.

Note: Limit this discussion to 2 single-spaced, type-written pages.

#### D. Service Area (geographic and demographic characteristics)

Each applicant will be evaluated on the population base the applicant identifies and the unemployment level in the area to be serviced. Demographic characteristics will be evaluated including the total population of the State and the percentage of the population to be served and the unemployment conditions in the area. The following criteria will be used to evaluate the application:

1. Highly acceptable—The applicant will service an area that consists of the lesser of either: (i) at least one million residents or (ii) at least 75% of the population of the State. In addition, the level of unemployment in the area to be serviced must be at least 1.25 times the national unemployment rate for the most recent 24 month period for which statistics are available.

2. Acceptable—The applicant will service an area that consists of the lesser of either: (i) at least five hundred thousand residents or (ii) at least 50% of the population of the State. In addition, the level of unemployment in the area to be serviced must be at least equal to the national unemployment rate for the most recent 24 month period for which statistics are available. In the event that the level of unemployment in the area to be serviced is at least 1.5 times the national unemployment rate for the most recent 24 month period for which statistics are available, then the number of residents to be serviced need only to exceed three hundred and fifty thousand.

3. Marginally acceptable—The applicant will service an area that consists of the lesser of either: (i) two hundred and fifty thousand residents or (ii) at least 25% of the population of the state. In addition, the level of unemployment in the area to be serviced must be at least equal to the national unemployment rate for the most recent 24 month period for which statistics are available. In the event that the level of unemployment in the area to be serviced is at least 1.5 times the national unemployment rate for the most recent 24 month period for which statistics are available, then the number of residents to be serviced need only to exceed one hundred and fifty thousand.

4. Unacceptable—The applicant will service an area that consists of neither: (i) two hundred and fifty thousand residents for areas where the level of unemployment in the area to be

served is less than 1.5 times the national unemployment rate for the most recent 24 month period for which statistics are available or one hundred and fifty thousand where the level of unemployment in the area to be served is at least 1.5 times the national unemployment rate for the most recent 24 month period for which statistics are available or (ii) at least 25% of the population of the State.

Note: Limit this discussion to 1 single-spaced, type-written page.

#### E. Cost Realism

Each applicant's response to this element will be evaluated for reasonableness and realism in managing cost. Implicit in the assessment is the need to demonstrate the relationship of the estimated overall program cost to the proposed level of performance. The applicant shall describe the measures intended to control, account for, and document relevant costs. For example, describe the ratio of program management cost to counselor cost and the ratio of program management cost to total program cost, with an objective of optimizing the percent of total program cost to be spent on direct counseling and assistance to clients. Unrealistic cost reflected in the application will be deemed indicative of the applicant's inability to perform the PTA Program. Such applications may also reflect lack of understanding of the complexity or the risks in scope of the requirement. As such, they will no longer be considered eligible for award.

The following criteria will be used to evaluate the application:

1. Highly acceptable—The applicant must demonstrate that its approach to cost management satisfies all PTA Program requirements in an above average manner.

2. Acceptable—The applicant must demonstrate that its approach to cost management is adequate to satisfy all PTA Program requirements.

3. Marginally acceptable—The applicant must demonstrate that it has the capability to satisfy the majority of the PTA Program requirements.

4. Unacceptable—The applicant has indicated through its response to this element that its cost management approach is inadequate to fulfill minimum PTA Program requirements.

Note: Limit this discussion to 1 single-spaced, type-written pages.

#### 3-9 Cost Sharing Limitations

##### A. General program.

1. The DoD share of net program cost shall not exceed 50%, except in a case where an eligible entity meets the

criteria for a distressed area. When the prerequisite conditions to qualify as a distressed area are met, the DoD share may be increased to an amount not to exceed 75%. In no event shall the DoD share of net program cost exceed \$150,000 for programs providing less than statewide coverage or \$300,000 for programs providing statewide coverage.

2. Consultant services provided by private nonprofit and/or profit making individuals, organizations or otherwise qualified business entities may be used to augment a cooperative agreement recipient's internal capabilities subject to the 10% total program cost limitation.

##### B. American Indian Program.

1. The DoD share shall not exceed 75% of net program cost or \$150,000 for a program providing service on reservations within one BIA service area, or \$300,000 for a program providing multi-area coverage.

2. Consultant services provided by private nonprofit and/or profit making individuals, organizations or otherwise qualified business entities may be used to augment a cooperative agreement recipient's internal capabilities subject to the 25% total program cost limitation.

C. The type and value of third-party in-kind contributions is limited to no more than 25% of total program cost. Third-party in-kind contributions shall meet the requirements set forth by subparagraphs 3-10E and 3-10F below.

D. Indirect cost and/or indirect rate used in the application are subject to downward revision only.

E. The applicant shall submit a copy of the current negotiated indirect rate memorandum issued by its cognizant Federal agency.

F. Indirect cost for educational institutions shall be limited to actual cost incurred for administration expenses and cannot exceed 26%.

#### 3-10 Cost Sharing Criteria

A. Cost contributions may be either direct or indirect costs, provided such costs are otherwise allowable in accordance with the applicable cost principles. Allowable costs which are absorbed by the applicant as its share of costs may not be charged directly or indirectly or may not have been previously charged, in part or in whole, to the Federal Government under other contracts, agreements, or grants.

B. Except as provided by Federal statute, a cost sharing or matching requirement may not be met by costs borne by another Federal grant.

C. Program income or other Federal funds, that are not authorized for use by Federal statute, (excluding loan guarantee agreements since these do not provide for disbursement of Federal

funds) are not acceptable for use as the applicant's cost matching funds. Inclusion of other Federal funds in the program as part of total program cost is subject to authorization by Federal statute and the terms of the instrument containing such funds or written advice obtained from the agency awarding the Federal funds. Any Federal funds used by the eligible entity, other than the DoD PTA Cooperative Agreement Program funds, must be disclosed and identified in the eligible entity's proposal.

D. Neither costs nor the values of third party in-kind contributions may count toward satisfying a cost sharing or matching requirement of the SCAP if they have been or will be counted toward satisfying a cost sharing or matching requirement of another Federal grant, a Federal procurement contract, or any other award of Federal funds.

E. All applicant contributions, including cash and third party in-kind, shall be accepted as part of the recipient's cost sharing or matching when such contributions meet all of the following criteria; (1) are verifiable from the records of recipients, subrecipients, or cost-type contractors (these records must show how the value placed on third party in-kind contributions was derived and to the extent feasible, volunteer services must be supported by the same methods that the organization uses to support the allocability of regular personnel costs); (2) are not included as contributions for any other federally-assisted project or program; (3) are necessary and reasonable for proper and efficient accomplishment of the project or program objectives; (4) are allowable under the applicable cost principles; (5) are not paid by the Federal Government under another award, except where authorized by Federal statute to be used for cost sharing or matching; (6) are provided for in the budget and (7) conform to other provisions for uniform administration requirements under the applicable OMB Circular.

F. Third party in-kind contributions may satisfy a cost sharing or matching requirement only when the payments would be allowable costs if the party receiving the contributions were to pay for them. Some third party in-kind contributions are goods and services that would have been an indirect cost if the recipient, subrecipient or contractor had been required to pay for them. Cost sharing or matching credit for such contributions may be given only if the recipient, subrecipient or contractor has established, along with its regular indirect cost rate, a special rate for

allocating to individual projects or programs the value of the contributions.

G. Where distressed funding (greater than 50%) is requested and the civil jurisdiction(s) which the applicant plans to service is both distressed and nondistressed, two budgets must be submitted identifying the anticipated distribution of total program cost between these two areas. In addition, the recipient's accounting system must segregate and accumulate costs in each of the two budget areas.

H. Recipients of PTA cooperative agreements are required to maintain records adequate to reflect the nature and extent of their costs and expenditures, and to ensure that their required cost participation is achieved.

### *3-11 Option To Extend the Term of the Cooperative Agreement*

A. A SCAA will be issued every third fiscal year, i.e., 1996, 1999, etc. Cooperative agreements will be awarded for a base year with one or two option periods of twelve months each.

B. The awarding of a cooperative agreement for a base year with one or two option periods of twelve months each does not guarantee the recipient that an option(s) will be exercised. The Government at its sole discretion may elect not to exercise an option(s), to exercise an option(s) or to replace an existing program with either another existing or new start program. The determination to exercise or not to exercise an option will be made on a program by program basis. Duplicate coverage, the number of DLA funded PTA centers operating in a state and DoD funds available may be considered when deciding to or not to exercise an option.

C. An option may be exercised by the Government providing the recipient's:

1. Demonstrated performance is equal or better than that required by the base year or first option year cooperative agreement award and a satisfactory or better performance rating is received from the cognizant administrative contracting officer.

2. Technical capability is equal or better than that required by the base year or first option year cooperative agreement award.

3. Cost matching funds are available.

4. Five client success stories that resulted from the direct and exclusive effort of the PTA center are verified by the Government and—

5. No other new application(s) (existing or new start) are received by DLA that can provide similar or better services at a lower cost to the Government.

D. The Government shall give the cooperative agreement recipient a preliminary written notice of its intent to extend the cooperative agreement performance period no later than 120 calendar days prior to the end of the Government's current fiscal year (1 October thru 30 September). The preliminary notice does not commit the government to an extension. The Government may extend the effective period of the cooperative agreement by giving written notice to the cooperative agreement recipient no later than 105 calendar days after issuance of the preliminary notice.

E. New applications for cooperative agreements must be submitted no earlier than 1 April and received no later than 30 April of each calendar year. The application shall be prepared in accordance with the most recent solicitation for cooperative agreement application. Generally, awards will be made during the month of July.

1. Applications received prior to April 30, 1996, if selected to receive an award, will be awarded for a base year with two option periods of twelve months each.

2. Applications received prior to April 30, 1997, if selected to receive an award, will be awarded for a base year with one option period of twelve months.

3. Applications received prior to April 30, 1998, if selected to receive an award, will be awarded for a base year only.

4. The base year application submitted prior to 30 April 1996 or 1997, unless otherwise extended, must include separate SF 424s and SF 424As for the option year(s). Detailed budget information for the option year(s) is not required to be submitted with the base year application. However, the net program cost and geographic area of coverage shall be the same for the option period(s) as that provided for the base year.

F. The notice of award for the base year will provide funding for a 12-month period only. Option year(s) are subject to the availability of funds as set forth by the clause entitled "Availability of funds."

G. Option Year(s) requirements.

Upon receipt of the Government's preliminary written notice of its intent to extend, at least 120 calendar days prior to the end of the Government's current fiscal year, the cooperative agreement recipient that desires exercising of the option, shall prepare and submit, to the Grants Officer no later than 30 calendar days after receipt of the Government's preliminary notice, the following:

1. Completed SF 424A for the option year with a complete narrative justification for budgeted costs.

2. Completed goal work sheet.

3. Copy of its current negotiated indirect cost rate agreement, if there are any changes.

4. Certification of cost match.

5. Updated personnel form.

6. Five client success stories that resulted from the direct and exclusive effort of the PTA center.

7. The number of jobs generated and/or retained resulting from the procurement technical assistance provided by the recipient.

8. A summary of its most recent 12-month performance period, description of how its program satisfies the criteria set forth below and justification for any funds that were deobligated.

H. Evaluation of past performance will be a subjective assessment based on a consideration of all relevant facts and circumstances. The most recent copy of the contract administration activity's Evaluation Report must be provided.

1. Highly acceptable—The application must demonstrate a high degree of success in satisfying all PTA Program requirements during the most current 12-month performance period. The evaluation report must substantiate that the applicant has an above average program.

2. Acceptable—The application must demonstrate that the applicant has met all PTA Program requirements during the most recent 12-month performance period. The evaluation report must substantiate that the applicant has an adequate program.

3. Marginally acceptable—The application must demonstrate that the applicant has satisfied most of the PTA Program requirements during the most recent 12-month performance period. The evaluation report must substantiate that the applicant has implemented most program requirements.

4. Unacceptable—The applicant has fulfilled few of the PTA Program requirements during the most recent 12-month performance period. The evaluation report must substantiate that the applicant has an inadequate program.

Note: Limit this discussion to 3 single-spaced, type-written pages.

### *3-12 Administration*

A. Cooperative agreements with state and local governments, nonprofit organizations and Indian economic enterprises will be assigned to the cognizant Defense Contract Management Command for administration. Cooperative agreements with educational institutions will be assigned to the Office of Naval Research for administration.

B. The organization having cognizance for postaward administration will periodically review the recipient's performance under the cooperative agreement to include:

1. management control systems;
2. financial management systems;
3. progress being made by the recipient in meeting its program requirements; and
4. compliance with certifications, representations and other performance factors. The cognizant Deputy for Small Business will be the focal point for the Administrative Contracting Officer for small business issues and for all recipient publication and training requests.

C. For recipients covered by OMB Circular No. A-102, Grants and Cooperative Agreements with State and Local Governments, or OMB Circular No. A-110, Grants and Agreements with Institutions of Higher Education, Hospitals and other Non-profit Organizations, the administrative requirements specified in those circulars will apply.

D. Each state and local entity that receives Federal funding is required to have audits performed in accordance with the requirements of OMB Circular A-128. Nonprofit organizations and institutions of higher education are required to have audits performed in accordance with the requirements of OMB Circular A-133. Indian economic enterprises (for profit only) will have audits performed in accordance with the requirements of OMB Circular A-133. Recipients shall submit one copy of any audit report that results from any audit performed pursuant to the requirements of the PTA cooperative agreement to the Office of the Assistant Inspector General for Audit, Policy and Oversight, Office of the Inspector General, 400 Army-Navy Drive, Room 1076, Arlington, VA 22202-2884.

E. The following OMB Circulars will be used to determine allowable costs in performance of the program:

1. OMB Circular No. A-21, Cost Principles for Educational Institutions;
2. OMB Circular No. A-87, Cost Principles for State and Local Governments; and
3. OMB Circular No. A-122, Cost Principles for Nonprofit Organizations. This circular will also be used by for-profit organizations.

[FR Doc. 96-5062 Filed 3-4-96; 8:45 am]

BILLING CODE 3620-01-P

## DEPARTMENT OF EDUCATION

### Notice of Proposed Information Collection Requests

**AGENCY:** Department of Education.

**ACTION:** Proposed collection; comment request.

**SUMMARY:** The Director, Information Resources Group, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

**DATES:** Interested persons are invited to submit comments on or before May 6, 1996.

**ADDRESSES:** Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Wendy Taylor, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10235, New Executive Office Building, Washington, DC 20503. Requests for copies of the proposed information collection requests should be addressed to Patrick J. Sherrill, Department of Education, 600 Independence Avenue, S.W., Room 5624, Regional Office Building 3, Washington, DC 20202-4651.

**FOR FURTHER INFORMATION CONTACT:** Patrick J. Sherrill (202) 708-8196. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

**SUPPLEMENTARY INFORMATION:** Section 3506 of the Paperwork Reduction Act of 1995 (44 U. S. C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Director of the Information Resources Group publishes this notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and

frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment at the address specified above. Copies of the requests are available from Patrick J. Sherrill at the address specified above.

Dated: February 28, 1996.

Gloria Parker,

*Director, Information Resources Group.*

Office of Special Education and Rehabilitative Services

*Type of Review:* Extension.

*Title:* Report of Children and Youth with Disabilities Receiving Special Education Under Part B of Individuals with Disabilities Education Act.

*Frequency:* Annually.

*Affected Public:* State, local or Tribal Gov't, SEAs or LEAs.

*Reporting Burden and Recordkeeping:* Responses: 58; Burden Hours: 15,196.

*Abstract:* This package provides instructions and forms necessary for States to report the number of children with disabilities served under the Individuals with Disabilities Education Act (IDEA)-B receiving special education and related services. It serves as the basis for distributing federal assistance, monitoring, implementing, and Congressional reporting.

Office of Special Education and Rehabilitative Services

*Type of Review:* Extension.

*Title:* Individuals with Disabilities Education Act, Part B, Implementation of FAPE Requirement.

*Frequency:* Annually.

*Affected Public:* State, local or Tribal Gov't, SEAs or LEAs.

*Reporting Burden and Recordkeeping:* Responses: 58; Burden Hours: 198,418.

*Abstract:* This package provides instructions and forms for States to report the setting in which children with disabilities served under the Individuals with Disabilities Education Act (IDEA)-B receive special education and related services. The form satisfies reporting requirements in this area and is used to monitor SEAs and for Congressional reporting.

Office of Special Education and Rehabilitative Services

*Type of Review:* Extension.

*Title:* Personnel Employed and Needed to Provide Special Education and Related Services for Children and Youth with Disabilities.

*Frequency:* Annually.

*Affected Public:* State, local or Tribal Gov't, SEAs or LEAs.

*Reporting Burden and Recordkeeping:* Responses: 58; Burden Hours: 10,585.

*Abstract:* This package provides instructions and forms for States to

report the number of personnel employed and needed in the provision of special education and related services. Data are obtained from state and local education agencies, and are used to assess the implementation of the Individuals with Disabilities Education Act (IDEA) and for monitoring, planning and reporting to Congress.

Office of Special Education and Rehabilitative Services

*Type of Review:* Extension.

*Title:* Report of Children and Youth with Disabilities Exiting Special Education During the 1996-97 School Year.

*Frequency:* Annually.

*Affected Public:* State, local or Tribal Gov't, SEAs or LEAs.

*Reporting Burden and Recordkeeping:* Responses: 58; Burden Hours: 16,124.

*Abstract:* This package provides instructions and a form necessary for States to report the settings in which children with disabilities served under Individuals with Disabilities Education Act (IDEA)-B receive special education and related services. The form satisfies reporting requirements and is used by the Office of Special Education Programs to monitor SEAs and for Congressional reporting.

Office of Special Education and Rehabilitative Services

*Type of Review:* Extension.

*Title:* Number and Type of Personnel Employed and Contracted and Additional Personnel Needed to Provide Early Intervention Services for Infants and Toddlers with Disabilities and Their Families.

*Frequency:* Annually.

*Affected Public:* State, local or Tribal Gov't, SEAs or LEAs.

*Reporting Burden and Recordkeeping:* Responses: 58; Burden Hours: 13,596.

*Abstract:* This package provides instructions and forms necessary for States to report the number of personnel employed and needed in the provision of early intervention services for infants and toddlers with disabilities served under Individuals with Disabilities Education Act (IDEA), Part H. Data are obtained from state and local service agencies and are used to assess the implementation of IDEA and for monitoring, implementing, and Congressional reporting.

Office of Special Education and Rehabilitative Services

*Type of Review:* Revision.

*Title:* Forms Clearance Package for the Projects with Industry Program.

*Frequency:* Annually.

*Affected Public:* Business or other for-profit; Not-for-profit institutions; State, local or Tribal Gov't, SEAs or LEAs.

*Reporting Burden and Recordkeeping:* Responses: 101; Burden Hours: 4,040.

*Abstract:* The purpose of collecting compliance indicator data on the Projects with Industry program is to comply with the Congressional mandate to assess project performances based on evaluation standards as established under the 1986 Rehabilitation Act Amendments.

Office of Special Education and Rehabilitative Services

*Type of Review:* Extension.

*Title:* Report of Infants and Toddlers Receiving Intervention Services in accord with Part H and Report of Early Intervention Services on IFSPS Provided to Infants and Toddlers and Their Families in Accord with Part H.

*Frequency:* Annually.

*Affected Public:* State, local or Tribal Gov't, SEAs or LEAs.

*Reported Burden and Recordkeeping:* Responses: 58; Burden Hours: 2,378.

*Abstract:* This package provides instructions and forms necessary for States to report the number of infants and toddlers with disabilities served under Individuals with Disabilities Education Act (IDEA), Part H receiving early intervention services and the services provided as indicated on the Individualized Family Service Plan (IFSP). Data are obtained from state and local service agencies and are used to assess the implementation of IDEA and for monitoring, implementing, and Congressional reporting.

Office of Special Education and Rehabilitative Services

*Type of Review:* Extension.

*Title:* Report of Program Settings Where Early Intervention Services are Provided to Infants and Toddlers with Disabilities and Their Families.

*Frequency:* Annually.

*Affected Public:* State, local or Tribal Gov't, SEAs or LEAs. *Reported Burden and Recordkeeping:* Responses: 58; Burden Hours: 928.

*Abstract:* This package provides instructions and forms necessary for States to report program settings where early intervention services are provided to infants and toddlers with disabilities served under Individuals with Disabilities Education Act (IDEA), Part H. Data are obtained from state and local service agencies and are used to assess the implementation of IDEA and for monitoring, implementing, and Congressional reporting.

Office of Postsecondary Education

*Type of Review:* New.

*Title:* Quick Response Information System (QRIS).

*Frequency:* One-time.

*Affected Public:* Not-for-profit institutions; State, local or Tribal Gov't, SEAs or LEAs.

*Annual Reporting and Recordkeeping Hour Burden:* Responses: 4,308; Burden Hours: 3,228.

*Abstract:* This is a request for system clearance of the QRIS survey system which consists of the Fast Response Survey System (FRSS) and, as of Fall 96, the Postsecondary Education Quick Information System (PEQIS). FRSS primarily conducts surveys of the elementary/secondary sector and public libraries while PEQIS focuses on the postsecondary education sector. The FRSS and PEQIS were established (in 1975 and 1991 respectively) to meet quick turnaround data requests of Department of Education and others with requirements for education data that are not available elsewhere and are needed to formulate policy; to make legislative, budgeting, and planning decisions for existing programs; and to develop new programs. The surveys are characterized by short survey forms with short response time and typical sample sizes of around 1,000. It is anticipated that about five surveys will be conducted under QRIS this year.

[FR Doc. 96-5052 Filed 3-4-96; 8:45 am]

BILLING CODE 4000-01-P

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## DEPARTMENT OF ENERGY

### Planning Guidance for Contractor Work Force Restructuring

**AGENCY:** Department of Energy.

**ACTION:** Notice of Interim Planning Guidance.

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**SUMMARY:** The Department of Energy today publishes for public comment interim Planning Guidance that has been issued to Department of Energy field organizations and other components responsible for planning and implementing contractor work force restructuring at defense nuclear facilities and other DOE facilities. The Guidance includes procedures, interpretations, and policies that the field organizations should use in developing site-specific plans consistent with section 3161 of the National Defense Authorization Act for Fiscal Year 1993. The Secretary has decided that the section 3161 planning process should apply, to the extent practicable and allowed by law, to work force restructuring at all Department of Energy facilities.



**DATES:** Written comments (7 copies) are due on or before May 6, 1996. The Guidance is effective upon publication in the Federal Register.

**ADDRESSES:** Comments must be submitted to: U.S. Department of Energy, Office of Worker and Community Transition, WT-1, 1000 Independence Avenue, S.W., Washington, D.C. 20585.

**FOR FURTHER INFORMATION CONTACT:** Ms. Deborah Sullivan, U.S. Department of Energy, Washington, D.C. 20585, phone: 202-586-0452.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The Department of Energy (Department or DOE) has broad authority to develop generally applicable policies covering all aspects of defense nuclear facilities. The Atomic Energy Act, 42 U.S.C. 161(i)(3) and 2201(p). In addition, section 3161 of the National Defense Authorization Act for Fiscal Year 1993, 42 U.S.C. 7274h, requires the Department to develop a plan for restructuring the work force at a defense nuclear facility whenever the DOE determines that a change in the work force is necessary. Defense nuclear facilities within the meaning of section 3161 include facilities conducting atomic energy defense activities involving production or utilization of special nuclear material, nuclear waste storage or disposal facilities, testing and assembly facilities, and atomic weapons research facilities. The Department has issued the Guidance published in this notice to assist field organizations in developing site-specific plans consistent with section 3161 and other applicable laws and is voluntarily publishing this Guidance for public comment. The Department intends to revise the Guidance periodically as appropriate in light of public comments and experience. Various inadvertent errors and possible ambiguities in the Guidance distributed on April 5, 1995, have been corrected and clarified in this version. One significant respect in which the Guidance has been clarified is to make it clear that all notices of involuntary reductions in force of more than 100 employees at a single site require specific Secretarial approval. Secretarial approval of a work force restructuring plan does not authorize a site to give involuntary separation notices without specific Secretarial approval for the involuntary separations, although specific Secretarial approval of the involuntary separations may be provided at the same time as approval of the plan. Section 3161 furthers President Clinton's

"Putting People First" policy, which emphasizes the importance of conserving and efficiently redirecting the Government's valuable human resources from pursuit of the Cold War to new missions. Some DOE defense nuclear facilities are being downsized as a result of decisions to reduce the nuclear weapons stockpile and terminate production of nuclear weapons. Another major change at DOE defense nuclear facilities has been the increase in recent years in environmental restoration and waste management activities. At other defense nuclear facilities, work force modification is needed because of different kinds of shifts in the mission of the facility. Still other work force changes are the consequence of reductions in the Department's budget. The essential requirement of section 3161 is that the DOE must develop work force restructuring plans to minimize the social and economic impacts of work force changes at defense nuclear facilities.

Section 3161(c) sets forth six objectives that shall guide the Department in preparing a work force restructuring plan for a defense nuclear facility. First, changes in the work force at a DOE defense nuclear facility: (1) should be accomplished so as to minimize social and economic impacts; (2) should be made only after the provision of notice of such changes not later than 120 days before the commencement of such changes to such employees and the communities in which such facilities are located; and (3) should be accomplished, when possible, through the use of retraining, early retirement, attrition, and other options that minimize layoffs.

Second, employees whose employment in positions at such facilities is terminated shall, to the extent practicable, receive preference in any hiring by the DOE (consistent with applicable employment seniority plans or practices of the DOE and with section 3152 of the National Defense Authorization Act for Fiscal Years 1990 and 1991 (Public Law 101-189; 103 Stat. 1682)). Third, employees shall, to the extent practicable, be retrained for work in environmental restoration and waste management activities at DOE facilities.

Fourth, the Department should provide relocation assistance to employees who are transferred to other DOE facilities as a result of the plan.

Fifth, the Department should assist terminated employees in obtaining appropriate retraining, education, and reemployment assistance (including employment placement assistance).

Sixth, the Department should provide local impact assistance to communities that are affected by the restructuring plan and coordinate the provision of such assistance with (1) programs carried out by the Department of Labor pursuant to the Job Training Partnership Act (29 U.S.C. 1501 et seq.); (2) programs carried out pursuant to the Defense Economic Adjustment, Diversification, Conversion, and Stabilization Act of 1990 (Part D of Public Law 101-510; 10 U.S.C. 2391 note); and (3) programs carried out by the Department of Commerce pursuant to title IX of the Public Works and Economic Development Act of 1965 (42 U.S.C. 3241 et seq.).

In establishing the Task Force on Worker and Community Transition on April 21, 1993, the Secretary of Energy directed that, for reasons of fairness, the planning process set forth in section 3161 should be applied, to the extent practicable and permitted by law, wherever work force restructuring takes place in the Department. On April 23, 1993, the Task Force issued draft General Planning Guidelines for Work Force Restructuring.

The formulation and execution of any work force restructuring plan is subject to the availability of appropriations, and differences in benefits provided at different sites or to defense and non-defense workers may reflect different levels of available funding.

##### **II. Stakeholder Participation in Work Force Restructuring Planning**

Pursuant to section 3161, all aspects of a defense nuclear facility work force restructuring plan, including the mix and level of benefits offered, shall be developed in consultation with affected DOE employees (including employees of Department contractors and subcontractors), representatives of collective-bargaining units of Department employees, interested Federal, State, and local government agencies, educational institutions and other institutions and groups in communities that will be affected by restructuring.

The Guidance provides that draft plans shall be distributed for stakeholder comment at appropriate points during the planning process. The Department will not approve Plans developed by field organizations unless there is a showing of meaningful stakeholder involvement in the planning process. The Guidance also identifies specific methods field organizations may use to obtain stakeholder input in the development of site-specific plans.



In addition to site-specific stakeholder involvement, the Department has involved stakeholders in work force restructuring policymaking at the national level. The Guidance published today reflects this extensive dialogue with stakeholders. Shortly after section 3161 was enacted, the Secretary of Energy established a Task Force on Worker and Community Transition to implement the new law and to address more generally the impacts of defense conversion. The Task Force held a National Stakeholders meeting on June 11, 1993, and published a report on July 29, 1993, that summarized issues raised by the stakeholders.

Based on continued stakeholder input and lessons learned from the ongoing development of site work force restructuring plans, the Department issued revised draft planning guidelines on March 24, 1994. Additional policy guidelines were subsequently included in a Report on the Department's Worker and Community Transition Program, issued by the Under Secretary on August 24, 1994. In September 1994, the Office of Worker and Community Transition replaced the Task Force and held a second National Stakeholders meeting on November 15–16, 1994. A third National Stakeholders meeting was held in Denver on April 20–21, 1995, and a fourth was held in Albuquerque on September 13–15, 1995. Another National Stakeholders meeting will be held in March 1996 in Atlanta.

### III. The General Purpose of the Interim Guidance

The interim Guidance published today was prepared by the Department's Office of Worker and Community Transition to plan for and mitigate the impacts of changes in the Department's contractor work force. The Guidance was developed to assist DOE field organizations that are primarily responsible for developing section 3161 plans. The Guidance sets forth generally non-prescriptive procedures for coordinating Department activities related to section 3161 planning, and contains interpretations and policy statements to help DOE field organizations implement section 3161 consistently with applicable contract provisions and other laws and obligations of the Department.

### IV. Request for Public Comment

Although not required by law, the Department has chosen to publish this revised interim Guidance for public comment so that all stakeholders and the general public have an opportunity to influence the general policies the

Department is following during the section 3161 planning process. The Department will publish final Guidance with appropriate revisions in light of the public comments and experience with the interim Guidance.

Although the public is invited to comment on all aspects of the Guidance, the Department is especially interested in receiving views on the following provisions:

#### A. The "Trigger" or Threshold for Section 3161 Planning

Section 3161 directs the Department to develop a plan when it is determined that "a change in the work force at a defense nuclear facility is necessary," and to submit the plan to Congress. The Department has interpreted section 3161 to apply only where a change in the nature or structure of the work force may affect 100 or more employees at a site within a 12-month period. While a formal plan is not required below this threshold, the Department will consider the objectives of section 3161 during the planning process in such cases.

#### B. Hiring Preference for "Employees Who Participated in Efforts To Maintain the Nation's Nuclear Deterrent During the Cold War"

The Guidance lists several benefits which field organizations should consider offering displaced workers, taking into account the skills of the workers at the affected site, overall budget constraints, contractual provisions, applicable pension and other benefits plans, and other legal requirements and obligations. However, the Guidance directs field organizations to provide a specific benefit—a hiring preference—to employees who participated in efforts to maintain the Nation's nuclear deterrent during the Cold War. This class of employees, in whom the Department has invested heavily to develop skills important to the Nation, is defined as employees who were working for a DOE contractor on September 27, 1991, the day the first unilateral reduction of the Nation's nuclear weapons stockpile was announced, and who have continued to work for DOE since that date, as set forth in greater detail in the attached Appendix D of the Guidance, which has been revised to correct inadvertent omissions in Appendix G as originally distributed on April 5.

The Guidance provides that employees who participated in efforts to maintain the Nation's nuclear deterrent during the Cold War, whose employment is terminated involuntarily (except those terminated for cause) and who are qualified for the job at the time

the work is to begin, shall receive preference in any hiring conducted by the DOE and its contractors and subcontractors (whose contracts equal or exceed \$500,000 in value) to fill vacancies, to the extent practicable and consistent with veterans' preference, other applicable law, employment seniority plans, and other legally binding preferences or practices, as set forth in greater detail in Section V.A. of the Guidance.

Nothing in the Guidance is intended to obligate a contractor to hire an employee who is not qualified to perform the work. The preference is not applicable in situations where positions become available and existing employees are offered a right of first refusal to those positions, e.g., where one contractor has replaced another and existing employees are offered a right of first refusal to employment with the replacement contractor.

#### C. Retraining for New Missions Including Cleanup

Section 3161 directs the Department, to the extent practicable, to retrain employees for environmental restoration and waste management activities at the site of their employment or at other DOE facilities. Eligibility for retraining benefits is not limited to employees who have been terminated during a work force restructuring.

The Guidance provides, in the "General Guidance" section, that early in the planning process, an analysis should be made of the facilities' future mission and the work force skills and capabilities that will be needed to fulfill that mission. The analysis should compare those future requirements with the skills and capabilities of current workers at the facility to identify workers who possess critical skills that will be needed for the future mission and to determine the retraining that will be necessary to provide existing employees with these skills.

Accordingly, the "Specific Benefits for Consideration" section provides that work force planning should identify training needs and provide the training to prepare the existing work force for the DOE's new missions (including environmental restoration and waste management). Furthermore, this section recommends a standard for determining whether retraining of employees for new missions, including cleanup, should be considered "practicable" under section 3161(c)(3). The recommended standard is that the training should be aimed at jobs for which (1) vacancies are expected in the near term and (2) training of current employees to fill those vacancies can be completed

within not more than six months at a cost of not more than \$10,000. (This training is different from the educational assistance provided for separated employees.)

#### V. Opportunity for Public Comment

Interested persons are invited to participate in this proceeding by submitting data, views, or comments with respect to today's notice.

Seven copies of written comments should be submitted to the address indicated in the **ADDRESSES** section of this notice. Comments should be identified on the outside of the envelope and on the documents themselves with the designation "Contractor Work Force Restructuring Guidance." In the event any person wishing to provide written comments cannot provide 7 copies, alternative arrangements can be made in advance with the Department.

All comments received will be available for public inspection as part of the administrative record on file for this matter in the Department of Energy Freedom of Information Office Reading Room, IE-090, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C. 20585, 202-586-6020, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, D.C. on February 1, 1996.

Robert W. DeGrasse, Jr.,  
*Director, Office of Worker and Community Transition.*

#### Interim Planning Guidance for Contractor Work Force Restructuring

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#### Interim Planning Guidance for Contractor Work Force Restructuring

##### I. Introduction

This planning guidance was prepared by the Department of Energy's Office of Worker and Community Transition (the Office) to plan for and mitigate the impacts of changes in the Department's contractor work force. The Office is directed to assure fair treatment of all concerned, while at the same time recognizing the unique conditions at each site and in each contract.

This guidance replaces guidelines issued by the Task Force on Worker and Community Transition on March 24, 1994. It is a product of the Department's experience over the past 2 years, and an extensive process of stakeholder and public involvement in shaping our worker and community transition policies. This process included national meetings on June 11, 1993, and on November 15 and 16, 1994. Comments were solicited from the public on a report, issued by Under Secretary Charles B. Curtis on August 24, 1994. Comments were also solicited on earlier versions of this guidance issued on April 22, 1993, and March 24, 1994. Additional stakeholder meetings were held on April 20 and 21, and September 13 through 15, 1995.

This guidance contains revisions and technical corrections to the document originally distributed on April 5, 1995. The Office intends to revise this interim guidance from time-to-time as warranted, based on comments received through notice and publication in the Federal Register, and other stakeholder comments and consultation.

Except where otherwise noted, this guidance is not prescriptive. Cognizant field organizations have responsibility for planning work force restructuring. The Department's field organizations are in the best position to conduct full consultation with affected stakeholders on these plans and to understand the unique needs of work force restructuring at field facilities. Points-of-contact at each field organization are listed in Appendix A.

##### II. Legislative Provisions

On April 21, 1993, Secretary of Energy Hazel R. O'Leary created a task force "to coordinate worker and community transition assistance as the Department goes through periods of changing priorities." In large measure, the task force was created to implement section 3161 of the National Defense Authorization Act (the Act) for Fiscal Year 1993. For reasons of fairness, the Secretary directed that the process set forth in section 3161 should be applied to the extent practicable wherever work force restructuring takes place in the Department.

Section 3161 requires the Secretary of Energy to develop a plan for restructuring the work force for a defense nuclear facility whenever there is a determination that a change in the work force is necessary. The plan is to be developed in consultation with local, state, and national stakeholders, and submitted to Congress 90 days after notice of a planned work force restructuring has been given to the affected employees and communities. A work force restructuring plan must be updated annually and should include an evaluation of the implementation of the plan during the preceding year.

Section 3161 of the Act provides specific objectives to guide the preparation of the plan to minimize worker and community impacts. The plan should provide at least 120 days notice to employees and communities prior to beginning any involuntary separations. Reductions should be accomplished, when possible, through use of retraining, early retirement, attrition, and other options that minimize layoffs. To the extent practicable, the Department should offer a hiring preference to involuntarily separated employees. Employees should, to the extent practicable, be retrained for work in environmental restoration and waste management. Employees transferred to other Department facilities should receive relocation assistance. Terminated employees should be assisted in obtaining reemployment assistance, including Out placement services,

appropriate retraining and education opportunities. The Department should provide local impact assistance to affected communities. Relevant sections of the Act are available from the sources listed in Appendix B.

Pursuant to section 3163, "defense nuclear facilities" for the purposes of section 3161 include the following types of facilities under the control or jurisdiction of the Secretary of Energy: atomic energy defense facilities involving production or utilization of special nuclear material; nuclear waste storage or disposal facilities; testing and assembly facilities; and atomic weapons research facilities. Department of Energy facilities that have been determined to be defense nuclear facilities for the purposes of section 3161 are listed in Appendix C.

### III. General Guidance

All work force changes, regardless of cause, should be managed by the cognizant field organization consistent with the objectives of section 3161 of the Act, and DOE Order 3309.1A covering Reductions in Contractor Employment.<sup>1</sup> Each plan should be developed by the field organization consistent with budget constraints, contractual provisions or other obligations. All aspects of a plan, including the mix and level of benefits offered, should be developed in consultation with the stakeholders at the affected facility, and other appropriate stakeholders to ensure, among other things, the judicious expenditure of public funds. The Office encourages field organizations to utilize the combination of work force restructuring mechanisms that will most effectively accomplish the restructuring objectives.

#### A. Threshold for Plans

Work force restructuring plans should be developed where changes in the nature or structure of the work force may affect 100 or more employees at a site within a 12-month period. Even when a full plan is not required, the objectives of section 3161 should be followed, to the extent practicable within available resources. While the objectives of section 3161 should be considered in cases of smaller reductions, the formal process required by the law is not necessary. Approval from the Office and the responsible program and funding office should be received before any work force change is implemented.

#### B. Timing of Plans

Upon determining that a change in the work force is necessary, the appropriate field organization should immediately begin planning for the restructuring, and develop a schedule for preparing a work force restructuring plan, if required. One of the objectives of the Act is to give at least 120 days notice to the employees before involuntary layoffs begin. Although a 120-day advance notification may not always be possible, every effort should be made to meet or exceed this important objective. Field organizations should work with the Office to develop a schedule for plan development that meets the needs of the site. The work force planning described below should occur on a timeline that supports this advanced notification objective, to the extent practicable.

#### C. Work Force Planning

The Office is developing an integrated process for a work force planning system, pursuant to the Secretary's direction. In the interim, we will employ the best possible work force planning practices available, consistent with the objectives set forth below.

Developing a baseline assessment of the skills and capabilities of the current work force should be the initial step in the work force planning process. Field organizations should then consider the future missions and budget estimates to project the required work force skills needed to achieve the desired outcomes. Strategies should be developed for making the transition from the current baseline to the projected need, including retraining, voluntary separation incentives, and reductions-in-force. Particular attention should be directed to ensuring that workers with critical skills are retained.

#### D. Local Impact Assistance to Communities

The work force restructuring plan should be developed in coordination with, and in support of, the economic development objectives of nearby communities. Therefore, local officials and institutions involved in mitigating social and economic impacts anticipated to be caused by the Department's actions should be consulted in development of the plan. The plan should provide demographic and skills information about the affected work force, as well as other data that could help frame the community's economic development challenges and options. It should also discuss benefits, such as education and training, that will be provided to eligible employees that

can augment community-based economic development initiatives. Finally, it should address ways the Department can support local business creation, expansion, and attraction activities. Separate guidance was issued August 24, 1994, on economic development efforts that may be supported by the Worker and Community Transition Program. Copies of this guidance may be obtained from the Office.

#### E. Stakeholder Input to Plans

Consultation with local, State, and national stakeholders, as well as State and local Government officials, is an essential element of the work force restructuring process. Input should be solicited and given consideration at appropriate points throughout the development of plans for work force restructuring. When possible, the Office recommends that field organizations make this Interim Planning Guidance available to their stakeholders in advance of the 120-day notification. This will give stakeholders a perspective on the parameters within which plans are prepared.

#### F. Role of Counsel

Work force restructuring raises many legal issues under a wide variety of statutes. Failure to comply with applicable laws can have significant consequences for both the Department and its contractors. It is therefore essential that counsel be involved in the formation and execution of the plans. Failure to present properly structured plans to the Office can result in delay and increased cost. Therefore, field organizations should include counsel as a member of the planning team.

#### G. The Role of DOE Contractors

While the Department may seek the assistance of its contractors in developing work force restructuring plans, the plans are Department of Energy products. In general, it is the Department's policy to make information available to the public that is available to the operating contractors and has bearing on the plans, unless such information is protected by law or regulation.

Department contractors are not identified by section 3161 of the Act as stakeholders who must be consulted in the preparation of work force restructuring plans. The exclusion of these contractors would be inappropriate, however, as they may be the principal resource of institutional knowledge on many restructuring issues, and may be the only source for certain information necessary for

<sup>1</sup> Order 3309.1A is being revised to incorporate the requirements of section 3161 of the Act and the organizational changes resulting from the creation of the Office of Worker and Community Transition.

preparing a plan. They are the employers of the affected employees and are generally the administrators of the pension and other benefit plans involved. They are responsible for fulfilling their obligations to bargain with the collective-bargaining representatives of their employees regarding changes in contracts, pension plans, other benefits, and any other mandatory bargaining issues necessitated by the restructuring plan, as well as for obtaining any waivers of claims or reemployment appropriate in any given situation. However, the Department is responsible for developing the plans.

#### *H. Approval of Plans*

By law, the Secretary submits work force restructuring plans to Congress, and thus is the official responsible for final approval. Involuntary separations should be carried out consistent with DOE Order 3309.1A, which requires prior notification to Headquarters. All notices of involuntary separation that affect more than 100 management and operating (M&O) employees at a single site require Secretarial approval. Early retirements and other voluntary separations may begin before final plan approval, after written approval by the Office, in order to reduce the number of involuntary layoffs. Draft plans should be submitted to the Office for concurrence prior to their release to stakeholders.

#### *I. Plan Updates*

Within a year of a work force restructuring plan's submission to Congress, or earlier if events suggest that it would be appropriate, the cognizant field organization should submit an update of the plan to the Office for the Secretary's approval and submission to Congress. The plan update, which is required by law, should evaluate the plan's implementation, including the number of workers receiving each benefit and the overall cost, and cost per participant of that benefit, together with information on retraining of retained employees, and subsequent reemployment of displaced workers. These plan updates should be provided to the Office for submission to the Congress even when a new plan is under development.

#### *J. Funding for Plans*

Limited funds are available for implementing the objectives of section 3161 of the Act for defense nuclear facilities, including economic development assistance. Funding for work force restructuring plans at facilities other than defense nuclear

facilities should be sought from the program responsible for the activities subject to the work force restructuring. Likewise, benefits for workers at defense nuclear facilities affected by the changes due to business or efficiency decisions should be sought from the appropriation of the program making the change. These decisions include initiatives such as privatization, commercialization and reductions aimed at achieving improved efficiency.

The allocation of funds to mitigate the impact of restructuring on the workers decreases the funds available for continuing program responsibilities and economic development. No "standardized" allocation of funds is contemplated as it is highly unlikely that the needs of any two work forces and communities undergoing a restructuring would be the same.

#### *IV. Specific Benefits for Consideration*

After work force planning has identified the classifications of workers at risk, consideration of specific benefits to mitigate involuntary separations should take into account available funding and the status of affected employees. In implementing the objectives of section 3161 of the Act, the Department recognizes a special responsibility to minimize the impact of work force restructuring on employees who were employed before September 27, 1991, the day President Bush announced the first unilateral reduction of the Nation's nuclear weapons stockpile, and the date the Department has chosen as the end of the Cold War. Appendix D contains the job attachment test that has been developed for determining those employees who participated in efforts to maintain the Nation's nuclear deterrent during the Cold War.

In developing a work force restructuring plan, the following benefits may be considered for affected workers. If adopted, specific offers and conditions should be described in the plan.

##### *A. Early Retirement*

The potential loss of employees with skills critical to achieving Departmental missions is a primary consideration in determining the appropriateness of early retirement incentives. When early retirement incentives are offered, it has generally been the Department's practice that the incentives are made available to all eligible employees. It is legally permissible to limit benefits by reasonable, objective categories such as job classification if such limitations do not give rise to unlawful discrimination or disparate impact of any kind.

Enumeration of employees by name, or criteria having substantially the same effect, is not generally considered reasonable, unless the employer has utilized written, objective and neutral criteria in the selection process. Early retirement incentive programs must be consistent with applicable contracts.

All proposed retirement incentives including lump sum payments, additional years of service or reduction in age penalties, should be analyzed with respect to the likely candidates to accept, and potential effects on critical skills. Employee Retirement Income Security Act (ERISA), Age Discrimination In Employment Act (ADEA), and other related legal concerns must be considered and resolved early in the process. It is essential that proposed early retirement programs receive appropriate actuarial validation establishing that they do not result in discrimination in favor of highly compensated employees within the meaning of the Internal Revenue Code, or in discrimination on the basis of any protected category of employees with respect to employment laws such as ADEA, Title VII of the Civil Rights Act, and the Americans with Disabilities Act.

Employees receiving an incentive to retire should not receive educational assistance or relocation assistance. It is anticipated that the value of early retirement incentives will exceed the value of the benefits provided to other separating employees. Any lump sum incentives paid to retirees in lieu of pension formula enhancements may not exceed his or her previous year's salary consistent with Department of Energy Acquisition Regulation Part 970.3102-2(1)(6) and Federal Acquisition Regulation Part 31.205-6(j)(7).

The cognizant field organization should adopt as part of its plan mechanisms to ensure that individuals accepting an early retirement incentive are not inappropriately rehired. Such mechanisms could include post-employment restrictions, requiring repayment of the incentive, and limiting the number of waivers of any such restrictions for critically skilled individuals.

##### *B. Voluntary Separation Incentives*

Voluntary separations may be encouraged by offering severance, or enhanced severance payments. Applications for voluntary separation may be refused in order to preserve critical knowledge or skills. Those volunteering for separation may be offered educational assistance, and relocation assistance, and they may

receive Displaced Workers Medical Benefits.

The cognizant field organization should adopt as part of its plan mechanisms to ensure that individuals accepting a voluntary separation incentive are not inappropriately rehired. Such mechanisms could include post-employment restrictions and require repayment of the incentive upon rehire. Individuals with critical skills should not be offered voluntary separation incentives unless sufficient personnel are available to fulfill mission requirements.

#### *C. Educational Assistance for Separated Employees*

Educational assistance should be considered for employees being voluntarily or involuntarily separated, except for employees accepting early retirement incentives. It is recommended that tuition assistance, and other reasonable and necessary educational expenses, be limited to not more than a total of \$10,000 over a period of not more than 4 years.

#### *D. Relocation Assistance*

Relocation assistance should be considered for workers being terminated and for those voluntarily separating, except for employees accepting early retirement incentives. Such assistance should particularly be considered for employees involuntarily separated who are hired at other Department facilities, but who do not qualify for relocation assistance under the hiring contractor's policies. It is recommended that relocation assistance include actual and reasonable expenses for transportation, movement of household goods, and temporary living accommodations within a range of \$2,000 to \$5,000.

#### *E. Retraining for New Missions Including Cleanup*

Work force planning should identify training needs and provide such training to transition the existing work force to new missions as early in the process as possible. The Office recommends that all retraining for cleanup or other missions meet the following practicability test: the training should be aimed at jobs for which vacancies are expected in the near term; and the training should be able to be completed within a reasonable time-frame in relationship to those vacancies (not more than 6 months), and at a reasonable cost (not to exceed \$10,000). The suggested \$10,000 cap includes tuition, course materials and related instructional costs, but not trainee salaries.

#### *F. Displaced Workers Medical Benefits*

Displaced Workers Medical Benefits, while not specifically mentioned in the objectives of section 3161 of the Act, should be offered to all employees of M&O or other prime contractors to the Department as an extension of current medical benefits eligibility. Department of Energy Acquisition Letter No. 93-4, dated April 7, 1993, establishes guidelines for implementing this program.<sup>2</sup>

Eligible employees include voluntarily and involuntarily separated employees of M&O contractors who are not otherwise eligible for such coverage under another program. Under certain circumstances, an employee may be able to continue coverage, at the employee's expense, for pre-existing medical conditions excluded from coverage under another plan for which he or she becomes eligible. Retirees who are provided medical coverage through retirement programs or Medicare are not eligible for this program.

During the first year following separation, the contractor will continue to pay its portion of the former worker's medical premium, and the former employee will pay his or her normal share. During the second year, the former employee will pay half of the Consolidated Omnibus Budget and Reconciliation Act (COBRA) rate. During the third and subsequent years, the former employee will pay the full COBRA rate.

#### *V. Mandatory Benefits*

The benefits described below must be offered to eligible employees:

##### *A. Preference in Hiring*

Section 3161 of the Act provides that, to the extent practicable, terminated employees at a defense nuclear facility should receive preference in filling vacancies in the work force of the Department of Energy and its contractors and subcontractors. The Department has determined that employees must be identified as having helped maintain the Nation's nuclear deterrent during the Cold War in order to qualify for this preference. The preference should be honored by all prime contractors, and by

subcontractors whose contracts with the Department equal or exceed \$500,000 in value.

The Department has established the following criteria for determining eligibility for the hiring preference: the individual must be a former employee (1) who was involuntarily terminated (except if terminated for cause); (2) who meets the eligibility standards in Appendix D; and (3) who is qualified for the job at the time the work is to begin. Where qualifications are approximately equal, eligible individuals will be given preference in hiring. However, the preference will be administered consistent with applicable law, regulation, or executive order, and collective bargaining agreements. This preference is not immediately applicable in situations where positions become available through an outsourcing action or follow-on contract in which the current employees should first be offered their same or similar job with the replacement contractor in order to avoid a layoff.

An individual's hiring preference continues until termination by the action (or inaction) of that individual. Initially, and on an annual basis thereafter, eligible individuals must certify their desire to retain their hiring preference. The Office has developed a Preference in Hiring Eligibility Form for this purpose (Appendix E) which eligible individuals should submit to their DOE field organization. Actions that would terminate an individual's hiring preference include: voluntary termination or termination for cause from a position that was obtained through the exercise of the preference, or failure to comply with the annual certification requirement.

The Department developed the Job Opportunity Bulletin Board System (JOBBS) to simplify implementation of the hiring preference by eligible individuals, and by contractors and subcontractors. Those individuals who have applied for and have been determined to be eligible for the preference may have their résumés entered into JOBBS where they will be specifically identified as job seekers with hiring preference. Companies doing new hiring for Department of Energy work should place job announcements into JOBBS. Contractors and designated subcontractors (those whose DOE contracts equal or exceed \$500,000 in value) will be instructed by the cognizant field organization to first seek eligible workers among those with the hiring preference listed in JOBBS. All other subcontractors should be encouraged to use JOBBS when hiring for DOE work. Eligible individuals who

<sup>2</sup> Subsequent to the issuance of Acquisition Letter No. 93-4, the Displaced Medical Benefits Program was expanded by memoranda to field organizations dated August 12, and December 2, 1993. The Department is currently revising Acquisition Letter No. 93-4 based on these memorandums. All separating employees of M&O contractors who were eligible for medical benefits prior to their separation from employment are eligible for continued coverage under the Displaced Workers Medical Benefits Program regardless of whether they meet the section 3161 job attachment test.

do not want to enter their résumés into JOBBS are responsible for informing potential employers of their preference.

Each field organization should develop procedures to ensure that the hiring preference is being honored by all prime contractors and designated subcontractors. The procedures should state that eligible individuals have the responsibility to: (1) Apply for the preference by submitting the Preference in Hiring Eligibility Form to the DOE field organization along with any necessary documentation for verification of their eligibility; (2) inform potential employers of their preference status; and (3) certify their continuing status through annual submission of the Preference in Hiring Eligibility Form. Field organization procedures should also describe how JOBBS can be used by eligible individuals to help fulfill these responsibilities and to aid their search for job openings that should honor the preference. The procedures may establish criteria for use by hiring contractors who must choose among eligible workers who are equally qualified for the same job opening. One example would be assigning a higher priority to candidates within commuting distance of the new job. The procedures should also describe how potential disputes will be resolved. The Office will review the field organization procedures. The procedures should be posted where other material of worker interest is normally posted, such as employee bulletin boards.

The Department encourages negotiation to incorporate the hiring preference by agreements for division of work and arrangements for accommodations of internal union rules that might otherwise be obstacles to implementation of flowdown of the hiring preference to applicable subcontracts. Field organizations may facilitate implementation of the hiring preference by developing subcontract award criteria or performance measures and related fee incentives based on the hiring preference.

#### *B. Construction Worker Benefit*

Construction wage rates and benefits are structured to take into account the intermittent nature of construction work. In recognition of this, early plans generally limited benefits for construction workers to tuition assistance, outplacement support, preference in hiring and relocation assistance. However, it has been noted that many construction workers have maintained long-term relationships with the Department, and structured their lives around work at our facilities. Many

of these relationships, which had been expected to continue, have been terminated as the general level of construction work declined following the end of the Cold War.

The Department has determined that construction workers who meet the job attachment test (Appendix D) may elect to receive a one-time benefit. In return for that benefit, these construction workers, like other employees, may be required to waive the hiring preference. The one-time benefit should be consistent with the employer's established separation pay benefit, if applied, but should not exceed 6 weeks at base pay rates. The specific amount of this benefit, as well as other benefits for construction workers should be defined during the plan development and stakeholder consultation process. The Office does not suggest that special payments should be made into either pension or health and welfare benefits funds for these workers. The Office does not view this special benefit as a precedent-setting action for the construction industry since this benefit carries out the intent of legislation that uniquely applies to the Department of Energy's Federal, contractor and subcontractor work force.

Construction workers who receive the special benefit should be restricted from employment at a Department facility for a period not less than the period equal to the salary value of the benefit without specific approval of the Department or pro rata repayment of this benefit.

#### *VI. Administrative Procedures*

This section describes the administrative procedures that should be followed in developing a new work force restructuring plan or for modifying an existing plan.

##### *A. 120-Day Notification*

Field organizations should notify workers and communities of impending work force restructuring at least 120 days prior to making any involuntary separations. The cognizant field organization should issue a general announcement to all employees, employee representatives, and to the community at large that work force changes are required at the facility. The draft announcement should be coordinated with the Office. We will seek concurrence from Congressional, Public, and Intergovernmental Affairs and the appropriate program offices. Field organizations should allow at least 1 week for Headquarters approval of 120-day announcements.

It is important that the notice emphasize that the estimate of employees affected set out in the 120-

day notice is a good faith estimate based on the information available at the time. The notice is the beginning of a downsizing process; this process and the related budget issues are necessarily fraught with uncertainties, making it difficult to predict the exact number of employees that will be affected. It is recognized that a 120-day notification may not be practicable under certain extraordinary circumstances; however, as much advance notice should be given as possible.

##### *B. Develop Baseline Data*

Field organizations should establish and maintain a baseline employment database that categorizes the total number of personnel employed on-site by contractor, program funding source and skill mix. As a basis for categorizing skills, the Office encourages field organizations to utilize the Common Occupational Classification System to ensure consistency across the Department. The baseline should also contain the number of people employed on a temporary or intermittent basis, and by subcontractor or support service contractors. Field organizations should provide this information to the Office on a quarterly basis. Field organizations are responsible for carrying out the data collection and analysis. Once the baseline information is established, the Office intends to conduct an independent audit to ensure data reliability, as appropriate in particular circumstances.

##### *C. Analyze Mission Requirements*

Field organizations should analyze, and revise as necessary, future mission requirements and the work force skills required to carry out those missions. Appropriate program offices are responsible for defining the parameters of the future missions. New or modified work force restructuring plans should include a detailed description of the methodology and analysis used to define the work force necessary to execute the missions.

##### *D. Identify Positions Excess to Future Requirements*

Based on the current work force, and the work force necessary to carry out future missions, the plan should identify the classification of employees that should be:

1. Retained because they possess critical skills;
2. Retained with little or no retraining;
3. Retained with appropriate retraining; and
4. Considered for voluntary separation incentives.

The analysis should also identify those job skills that are unlikely to be satisfied by existing workers.

#### *E. Stakeholder Involvement*

Early involvement of stakeholders in developing a work force restructuring plan is essential to identify and address issues and concerns that might impede the implementation of the plan. Stakeholders should also be given appropriate opportunity to comment on drafts of any new or modified work force restructuring plan as soon as the draft plan has been cleared by the Office for release to the public. The Office will endeavor to concur on draft plans within 2 weeks of submission.

Stakeholder input may be received at public meetings, or through written or oral comments. Comments and suggestions of all stakeholders are important and should be considered in developing the final plans and incorporated where appropriate. For those comments and suggestions not incorporated in the draft plans, a brief explanation of the reason for not doing so should be documented. Every effort should be made to make the plan approved by the Secretary available to each stakeholder who commented on an earlier draft of the plan. A discussion of stakeholder involvement should be included as part of each plan.

#### *F. Develop Voluntary Separation Program*

After appropriate work force planning has been completed, field organizations should consider voluntary separation incentives to facilitate work force transition. Voluntary incentives must be approved in writing by the Office. Such approval can be sought, and the incentive can be offered, prior to completion of any new or modified work force restructuring plan.

Retirement incentives, accompanied by the appropriate analysis, should be presented for approval to the Office. The Office will coordinate analysis and evaluation of proposals with the Office of Procurement and Assistance Management, the Office of General Counsel, and the program office. Employees being offered early retirement or voluntary separation incentives must receive sufficiently specific information to satisfy ERISA requirements.

Early retirement incentives will be evaluated for their consistency with maintaining critically needed skills and any request should include a full justification in conformance with this requirement. Field organizations should provide an assessment of the costs and benefits of the proposed voluntary

incentives, particularly in work force transitions designed to increase organizational efficiency. Field organizations should plan to provide at least 2 weeks for review by the Office and appropriate headquarters organizations.

Voluntary separation programs should not be offered to employees at the same time as early retirement programs, except in special circumstances and with prior approval. Voluntary incentive programs should be completed prior to any involuntary separations.

In exchange for the enhanced benefits employees receive in a voluntary separation program, it is the Department's policy to obtain from employees who separate under such a program a release of claims related to their employment and separation. The Department has adopted a model form of release, which is provided in Appendix F. Variations from the model may be required by state law or other special circumstances. However, departures from the model will require Department approval, including from the Office of General Counsel.

#### *G. Plan Approval*

The Office will coordinate the appropriate review by other Headquarters offices before concurring with plans or approving requests to implement voluntary incentive programs. In general, the Office will seek review from the affected program office, General Counsel, Field Management, and Human Resources and Administration. Field organizations should allow 1 month for Secretarial approval of final Work Force Restructuring Plans.

Thirty copies, plus 1 reproducible master, of the final plan should be submitted to the Office for subsequent submission by the Secretary to the appropriate Congressional committees and delegations from affected States. The responsible field organization should also make distribution to interested local stakeholders, and to the points-of-contact at each cognizant field organization. The Office will make additional copies, if necessary, from the master for distribution within Headquarters and to interested national stakeholders.

#### *H. Involuntary Separation*

In general, involuntary separation notices may not be given until after Secretarial approval. The notices should identify the specific numbers and job titles to be laid off. Each affected individual should be notified of his or her termination. Involuntarily separated

employees shall be fully advised of any benefits or services for which they are eligible. Appropriate labor representatives should be notified and letters prepared for local, county and state governments.

If layoffs are required that fall under the provisions of the Worker Adjustment and Retraining Notification Act (WARN), the employers must give the affected employees written notice of the layoffs at least 60 days prior to the date of the intended layoff. Employers may conduct the involuntary layoff by providing written notice to the affected employees that their termination date will occur 60 days thereafter. Compensation will continue during the 60-day period following the notice and where appropriate, employees may be excused from some or all duties during that period. If, during the 60-day period, an employee successfully obtains new employment, the employee must terminate the current employment relationship before beginning the new job, at which time the remaining salary payments shall cease. If this salary was paid in a lump sum, the pro rata share attributable to the period after the employee commences the new employment should be repaid. Repayment terms should be established within the restructuring plan and explained to employees during the exit interview process.

As a goal, all affected employees should receive their individual notification 60 days before layoff. When this is not possible, and the work force change is not subject to the provisions of the WARN Act, affected workers should receive as much layoff notice as practicable, but not less than 14 days. Intermittent workers are terminated when their work is completed.

#### *I. Outplacement Assistance*

Field organizations may provide Outplacement assistance (including training and education) to voluntarily separated employees as soon as they exercise that option, and to involuntarily separated employees as soon as they are notified. Appropriate outplacement assistance can also be made available to employees who may be at risk after the 120-day announcement has been made. Outplacement assistance should be planned in advance and should be appropriate in light of the number of employees expected to need such assistance. Field organizations are encouraged to track the employment, education, and insurance status of displaced workers for at least 1 year after separation.



*J. Budgeting for Plans*

Plans must include a budget estimate for each initiative or benefit planned for mitigating impacts on workers. Budget estimates should be based on a realistic projection of the number of workers who will participate in each initiative and reflect the best cost estimates available. Estimated incremental costs to pension funds for early retirements should be based on actuarial estimates. It is not acceptable to request funds based simply on maximum possible participation in each initiative or benefit. For planning purposes, an average cost of \$15,000 to \$25,000 per position eliminated is a reasonable range for guiding decisions about the range of benefits offered. Where work force restructuring is justified by business efficiency decisions, the budget estimates should be accompanied by savings estimates and the proposed use of those savings. In general, funding authorizations will be made following final approval of a plan. Funding authorizations for certain initiatives, such as those encouraging voluntary separations, may be made earlier.

Appendix A—Office of Worker and Community Transition Contacts

Director:

Bob DeGrasse—202-586-7550, FAX 586-8403

Deputy Director:

Terry Freese—202-586-5907, FAX 586-8403

Work Force Restructuring:

Terry Freese—202-586-5907, FAX 586-8403

Lew Waters—202-586-4010, FAX 586-8403

Work Force Planning:

Debby Swickow—202-586-0876, FAX 586-8403

Lew Waters—202-586-4010, FAX 586-8403

Labor Relations:

Lyle Brown—202-586-0431, FAX 586-8403

Deborah Sullivan—202-586-0452, FAX 586-1540

Community Transition:

Bob Baney—202-586-3751, FAX 586-1540

Mike Mescher—202-586-3924, FAX 586-1540

Debby Swickow—202-586-0876, FAX 586-8403

Public Participation:

Laurel Smith—202-586-4091, FAX 586-8403

Work Force Restructuring Field Contacts

Felix Ortiz, Albuquerque Operations Office—505-845-4207, FAX 845-4715

Elaine Kocolowski, Chicago Operations Office—708-252-2334, FAX 252-2919

Luella Bennett, Idaho Operations Office—208-526-1913, FAX 526-5969

Bob Agonia, Nevada Operations Office—702-295-1005, FAX 295-1876

Bill Truex, Oak Ridge Operations Office—423-576-0662, FAX 576-6964

Harry Printz, Oakland Operations Office—510-637-1829, FAX 637-2008

Ken Briggs, Ohio Field Office—513-865-4267, FAX 865-4312

Dom Sansotta, Richland Operations Office—509-376-7221, FAX 376-5335

Lenora Lewis, Rocky Flats Field Office—303-966-4263, FAX 966-3321

Dave Hepner, Savannah River Operations Office—803-725-1206, FAX 725-5968

Gil Gilyard, Savannah River Operations Office—803-725-7645, FAX 725-7631

Pat Lillard, Kansas City Area Office—816-997-3348, FAX 997-5059

Alan Goetz, Pinellas Area Office—813-541-8114, FAX 541-8370

Gene Gillespie, Portsmouth Site Office—614-897-2001, FAX 897-2982

Jimmie Hodges, Paducah Site Office—502-441-6800, FAX 441-6801

Appendix B—Statement of Availability

Sections 3161 and 3163 of the National Defense Authorization Act for Fiscal Year 1993 (Public Law 102-484, October 23, 1992) are available from the Superintendent of Documents, the Government Printing Office, the Office of the Federal Register, by contacting Laurel Smith from the Office of Worker and Community Transition, Department of Energy or on the Office of Worker and Community Transition Home Page under "Documents for Review and Comment." (<http://www.stat-usa.gov/owct.html>)

Appendix C—Listing of Defense Nuclear Facilities

The list below reflects facilities receiving funding for Atomic Energy Defense activities of the Department of Energy, with the exception of activities under Naval Reactor Propulsion. It is recognized that these facilities have varying degrees of defense activities, ranging from a total defense dedication to a very small portion of their overall activity. This may cause certain difficulties in implementing the intent of the section 3161 legislation. Regardless, this listing will be used by the Office for possible application of funding received for defense worker assistance and community transition purposes.

Kansas City Plant

Pinellas Plant

Mound Facility

Fernald Environmental Management Project Site

Pantex Plant

Rocky Flats Environmental Technology Site, including the Oxnard Facility

Savannah River Site

Los Alamos National Laboratory

Sandia National Laboratory

Argonne National Laboratory

Brookhaven National Laboratory

Lawrence Livermore National Laboratory

Oak Ridge National Laboratory

Nevada Test Site

Y-12 Plant

K-25 Plant

Hanford Site

Idaho National Engineering Laboratory

Waste Isolation Pilot Project

Portsmouth Gaseous Diffusion Plant  
Paducah Gaseous Diffusion Plant

Appendix D—Job Attachment Test

In implementing the objectives of section 3161 of the Act, the Department recognizes a special responsibility to minimize the impact of work force restructuring on employees who participated in efforts to maintain the Nation's nuclear deterrent during the Cold War. September 27, 1991, the day President Bush announced the first unilateral reduction of the Nation's stockpile, has generally been recognized by this Department as the end of the Cold War.

In general, employees who meet the job attachment test discussed below should be eligible for most benefits offered in a work force restructuring plan. However, the benefits offered at a specific site should be tailored to specific conditions, to the demographics of the workers at that site, and must be practicable and reasonable with respect to budget constraints, contractual provisions, and other obligations. Thus, those who meet the job attachment test are not likely to be offered exactly the same benefits at all sites.

To identify employees who helped maintain our nuclear deterrent during the Cold War, the criteria listed below should be followed at all sites:

A. Regular Employees

1. Must have been working at a defense nuclear facility on September 27, 1991;

2. Must have worked full-time (or regular part-time) at a facility from that date through the date of the 120-day notification; and

3. Must accept a voluntary separation incentive or have been involuntarily separated.

B. Intermittent Workers, Including Construction Workers

1. Must have worked at a defense nuclear facility on or before September 27, 1991;

2. Must have worked at a facility within 180 days preceding the work force restructuring notification;

3. Must have worked at a facility a total time, including time worked prior to September 27, 1991, equivalent to an employee having worked full-time from September 27, 1991 to the date of the 120-day notification, or have actually worked the industry standard of full-time from September 27, 1991 through the date of the 120-day notification; and

4. Must have been affected by the announced restructuring within a reasonable period of time (1 year is suggested). For an intermittent worker,



this includes the interruption of a project before its anticipated completion, or the completion of the assignment or project without prospect for a follow-on assignment at the site where the employee had a reasonable expectation of a follow-on assignment.

#### Appendix E—Example of Form for Establishing Preference in Hiring

##### Statement of Interest in Maintaining Section 3161 Employment Eligibility

Name: \_\_\_\_\_  
 First Middle Last  
 Social Security Number: \_\_\_\_\_-\_\_\_\_-\_\_\_\_  
 Address: \_\_\_\_\_  
 Street \_\_\_\_\_

Apartment No. \_\_\_\_\_

City State Zip  
 Telephone No. (\_\_\_\_) \_\_\_\_\_-\_\_\_\_\_  
 Date of Lay-off resulting from Work Force  
 Restructuring: \_\_\_\_\_ (Month/Day/  
 Year)

Occupational Classifications held: \_\_\_\_\_

I hereby request that my name be placed, or retained, on the Section 3161 Preference in Hiring List for the (*site name*) and be considered for any job opportunities that may arise for which I am qualified at this or any other Department of Energy site. I also certify that I have not been terminated for cause from employment by a Department of Energy Contractor or Subcontractor while performing work at a Department of Energy site.

Signature \_\_\_\_\_

Date \_\_\_\_\_

#### Appendix F—Sample Release for Use in Work Force Restructuring Programs

##### Voluntary Separation Payment Program General Release and Waiver

This Voluntary Separation Payment Program, General Release and Waiver ("Agreement") is entered into by and between \_\_\_\_\_ ("Employee") and \_\_\_\_\_ ("Employer"), as part of Employee's voluntary election to terminate employment with the Employer.

In Exchange for the Promises Set Forth Below, the Parties Agree as Follows:

1. Employee voluntarily terminates his/her employment with Employer effective \_\_\_\_\_, 1995. Employee agrees not to seek employment with or become employed at the \_\_\_\_\_ Site by the Employer or any other future or current contractor or subcontractor at the Site for a period of \_\_\_\_\_ year(s) from the date of Employee's resignation. This includes but is not limited to temporary employment service contracts, general task order assignments, indefinite quantity contracts, basic ordering agreements, and consultant contracts. However, this does not preclude Employee

from employment with a company providing supplies, equipment, materials, or commodities to the Site under a fixed-price contract or purchase order.

2. Employee agrees that the Employer has no obligation to reemploy Employee in the future, and Employee waives any recall, rehire, or rehire preference rights, such as those that may arise under Section 3161 of the National Defense Authorization Act for Fiscal 1993. Employee agrees to perform all steps required by Employer's policies and procedures at the separation of his/her employment.

3. Except as set forth in paragraph 4 below, Employee, on behalf of himself/herself and any person or entity entitled to sue on Employee's behalf, waives and releases Employer, its parents, subsidiaries, and affiliates, the Department of Energy, and their employees, officers, directors, shareholders, agents, and successors from any causes of action or claims, whether known or unknown, that arise out of the Employee's resignation and separation of employment with Employer and any causes of action or claims that arise out of Employee's employment with Employer, up to and including the date of Employee's resignation, under any federal, state or local law, including but not limited to the Age Discrimination in Employment Act, the Older Workers Benefit Protection Act of 1990, Title VII of the 1964 Civil Rights Act, the Equal Pay Act, the Family and Medical Leave Act, the Employee Retirement Income Security Act, and the Americans with Disabilities Act, or applicable state or local law. Employee will not assert any claim or cause of action released under this agreement in any administrative or judicial proceeding.

However, Employee does not waive:

(i) Any causes of action or claims that arise out of Employee's employment with Employer, up to and including the date of Employee's resignation, that have been asserted in writing and filed with the appropriate agency or court prior to the date on which this Program was announced;<sup>1</sup>

(ii) Any rights or claims that may arise after the date this Agreement is executed,

(iii) Any claims relating to pension or retiree health benefits that currently may be accrued under the Company's standard retirement program,

(iv) Any claims under any applicable state worker's compensation laws, or

(v) Any claims for occupational injuries or illnesses arising from Employee's employment with Employer that are not known or reasonably knowable by the Employee at the time of the execution of this Agreement.

5. In exchange for Employees' voluntary separation and execution of this Agreement, Employer will give Employee the consideration and benefits outlined in the description attached to this Agreement. The identification number or other designation for the document describing the benefits constituting consideration for this Agreement should be inserted at this point.<sup>2</sup>

6. If Employee becomes employed as prohibited in paragraph 1 or otherwise violates any provision of this Agreement, then, in addition to any other remedies

Employer has under this Agreement, Employer may require Employee to repay payments or other benefits under this Agreement, and Employee agrees to such repayment.

7. Employee has been advised to consider this Agreement and to consult with an attorney of his/her choice, and Employee has had the opportunity to do so. Employee has had the right to consider this Agreement for a period of at least forty-five (45) days prior to entering into this Agreement. Employee has the right to revoke this Agreement for a period of seven (7) days following execution of this Agreement by giving written notice to the local Human Resources representative. If Employee revokes the Agreement, it shall not be effective and enforceable and Employee will not receive any of the benefits described in paragraph 5. Employee has read and understands the terms and contents of this Agreement, and Employee freely, voluntarily, and without coercion enters into this Agreement and agrees to be bound by its terms.

8. This Agreement constitutes the entire understanding and agreement of Employee and Employer and can only be modified in writing agreed to by both parties.

9. Employee has received all of the information required to be disclosed in these circumstances under the Age Discrimination in Employment Act regarding who is covered by the Program, the eligibility factors, the time limits of the Program, the ages and job titles of everyone eligible for the Program, and the ages of ineligible employees in the same job classification or organizational unit.

Please Read This Agreement Carefully. It Contains a Release of Known and Unknown<sup>3</sup> Claims as Described in Paragraph 3, Above, Subject To The Limitations Expressly Set Forth in Paragraph 4.

Agreed to:

Employee/date \_\_\_\_\_

{Employer}/date \_\_\_\_\_

Notes:

1. The issuing organization should insert at this point a *specific date* on which the Separation Program involved was first announced. In determining this date, the issuing organization should consider the specificity of information provided to the public in work force restructuring plans issued pursuant to section 3161, as well as the announcement of the individual separation program involved.

2. When this Agreement is used in association with early retirement programs, the following language should be added here: "Employer reserves the right to provide equivalent benefits in another form in the unlikely event that any aspect of the Program is improper under law."

3. Counsel should check to be sure that this aspect of the Model Release fully comports with applicable state or local law.

[FR Doc. 96-4401 Filed 3-04-96; 8:45 am]

BILLING CODE 6450-01-P

[Docket No. CP96-199-000]

**Federal Energy Regulation Commission****Egan Hub Partners, L.P., Notice of Application**

February 28, 1996.

Take notice that on February 16, 1996, Egan Hub Partners, L.P. (Egan Hub) filed an application in Docket No. CP96-199-000 pursuant to Section 7(c) of the Natural Gas Act and Parts 157 and 284 of the Commission's Regulations (regulations) requesting: (1) a certificate of public convenience and necessity pursuant to Subpart A of Part 157 authorizing the operation of natural gas facilities initially constructed to provide Natural Gas Policy Act (NGPA) Section 311(a)(2) storage and transportation services at market-based rates; (2) a blanket certificate pursuant to subpart G of Part 284 authorizing Egan Hub to provide open access storage and transportation services on behalf of others; (3) a blanket construction certificate pursuant to Subpart F of Part 157 authorizing certain construction and operation of facilities abandonments, and certificate amendments; (4) a blanket sales certificate pursuant to Subpart J of Part 284 authorizing Egan Hub to provide unbundled sales service for the limited purpose of disposing of gas in storage that shippers may fail to remove; and (5) approval of the FERC Gas Tariff included at Exhibit P to the application; all as more fully set forth in the application on file with the Commission and open to public inspection.

Egan Hub also requests, if market-based rates are approved, waivers of (1) the requirements of Section 284.8(d) of the regulations, which require that rates be designed using a straight fixed-variable rate design methodology; (2) the requirements of Section 157.14 of the regulations to permit Egan Hub to omit Exhibits K, N, and O to the application; and (3) the accounting and reporting requirements under Part 201 and Section 260.2 of the regulations.

The storage and transportation facilities for which Egan Hub seeks approval to operate are located in Acadia Parish, Louisiana. Egan Hub says the facilities consist of an underground storage cavern and related natural gas transportation facilities which were initially constructed to provide NGPA 311(a)(2) service. Approval is requested to operate the existing storage cavern with a 3.5 Bcf working gas capacity and pipeline facilities consisting of:

- 1.75 miles of dual 20-inch pipeline and 3.62 miles of dual 20-inch pipeline

interconnecting Egan Hub with Trunkline Gas Company, ANR Pipeline Company, Tennessee Gas Pipeline Company, and Texas Gas Transmission Corporation; and

- 6.70 miles of 24-inch pipeline interconnecting Egan Hub with Columbia Gulf Transmission Company.
- Egan Hub proposes to charge and collect market-based rates for these storage and transportation services.

Egan Hub also requests a certificate of public convenience and necessity pursuant to Subpart A of Part 157 authorizing construction and operation of a second cavern and appurtenant facilities necessary to provide additional new storage and transportation services at market-based rates. The Commission's Staff will defer processing this request pending NE Hub's filing a supplement to this application which specifically describes the proposed new facilities and services and includes required environmental and engineering/geological data.

Any person desiring to be heard or to make any protest with reference to said application should on or before March 6, 1996, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceedings. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be

unnecessary for Edgan Hub to appear or be represented at the hearing.

Lois D. Cashell,

*Secretary.*

[FR Doc. 96-5077 Filed 3-4-96; 8:45 am]

BILLING CODE 6717-01-M

**Federal Energy Regulatory Commission**

[Docket No. TM96-4-34-000]

**Florida Gas Transmission Company; Notice of Proposed Changes in FERC Gas Tariff**

February 28, 1996.

Take notice that on February 23, 1996, Florida Gas Transmission Company (FGT) tendered for filing to become part of its FERC Gas Tariff, Third Revised Volume No. 1, effective April 1, 1996, the following tariff sheets:

Thirteenth Revised Sheet No. 8A  
Seventh Revised Sheet No. 8A.01  
Fifth Revised Sheet No. 8A.02  
Eleventh Revised Sheet No. 8B  
Fourth Revised Sheet No. 8B.01

FGT states that the instant filing is submitted pursuant to Section 27 of the General Terms and Conditions (GTC) contained in FGT's Tariff which provides that FGT will file a Fuel Reimbursement Charge Adjustment to be effective each April 1 and October 1, as applicable. Section 27.A. of the GTC provides for the submission of workpapers supporting any revisions to the Fuel Reimbursement Charge Percentage at least thirty days prior to the proposed effective date of the adjustment. Section 27.C. states that the Current Fuel Reimbursement Charge Percentage will be the quotient resulting from fuel used and lost and unaccounted for gas, less fuel retained for Western Division transportation service, divided by volumes delivered, excluding Western Division deliveries, during the six-month period commencing one year prior to the effective date of the Fuel Reimbursement Charge Adjustment.

FGT states the historical figures for the six-month period of April through September, 1995, reflect an extremely high utilization of FGT's newly expanded system. These historically high throughput levels of 264,362,538 MMBtu, or over 1,444,000 MMBtu per day, were in large part a result of the economic attractiveness of natural gas compared to alternate fuels for the generation of electricity. The total throughput included 9,967,431 MMBtu, or over 54,000 MMBtu per day, transported under FGT's interruptible rate schedules. While FGT historically

experiences high load factors during the summer period, FGT does not expect to achieve the levels of throughput which were transported from April through September 1995 because natural gas currently is selling at a considerable premium over alternate fuels which can be utilized by FGT's electric generation customers.

FGT further states because fuel usage is a function of throughput on FGT's system, and because of the expectation that throughput during the upcoming Summer period will be reduced from prior levels, FGT believes that collecting the 3.54% in-kind fuel reimbursement supported by the historical figures will result in an overcollection of fuel on a current basis. Consequently, the instant filing reflects an adjustment to the historical fuel usage percentage. This adjustment is calculated by dividing projected throughput for the upcoming Summer period of 1,390,137 MMBtu per day (historical deliveries net of interruptible transportation—approximately 96% load factor) by the 1,444,604 MMBtu per day of actual throughput from April through September of 1995, and multiplying that ratio times the fuel use experienced during the historical period. As a result of this adjustment, FGT is proposing a Current Fuel Reimbursement Charge of 3.41%.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426 in accordance with §§ 385.211 and 385.214 of the Commission's Rules and Regulations. All such motions or protests should be filed as provided in § 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,  
*Secretary.*

[FR Doc. 96-5067 Filed 3-4-96; 8:45 am]

BILLING CODE 6717-01-M

**[Docket No. RP96-148-000]**

**National Fuel Gas Supply Corporation;  
Notice of Tariff Filing**

February 28, 1996.

Take notice that on February 23, 1996, National Fuel Gas Supply Corporation

(National) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, the following tariff sheets proposed to be effective April 1, 1996:

Fourth Revised Sheet Nos. 1 and 2;  
Twelfth Revised Sheet No. 6;  
Original Sheet Nos. 97A through 97M;  
First Revised Sheet No. 150;  
Fourth Revised Sheet No. 205;  
First Revised Sheet No. 210F;  
Second Revised Sheet Nos. 211 and 212;  
Fourth Revised Sheet Nos. 236 and 237; and  
Original Sheet Nos. 284A through 284F

National states that these tariff sheets propose to include a new FSS-ST Rate Schedule to provide an option for customers to purchase firm storage service on a short-term basis. This new rate schedule will give National additional flexibility in re-marketing 3.2 Bcf of firm storage capacity formerly sold under the SS-1 and SS-2 Rate Schedules which will be turned-back on March 31, 1996, pursuant to written notices of termination.

National further states that copies of this filing were served upon the company's jurisdictional customers and upon the Regulatory Commission of the States of New York, Ohio, Pennsylvania, Delaware, Massachusetts, and New Jersey.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 North Capitol Street, N.E., Washington, D.C., 20426, in accordance with Rules 211 or 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 or 385.214). All such motions or protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,  
*Secretary.*

[FR Doc. 96-5070 Filed 3-4-96; 8:45 am]

BILLING CODE 6717-01-M

**[Docket No. RP94-206-001]**

**Pacific Gas Transmission Company;  
Notice of Report of Linepack Sales**

February 28, 1996.

Take notice that on February 23, 1996, Pacific Gas Transmission Company (PGT), filed its Annual Report of Linepack Sales, pursuant to Office of Pipeline Regulation Letter Order of

March 31, 1995 and Section 284.288 of the Commission's Regulations.

PGT states that it had no linepack sales during calendar year 1995. PGT further states that a copy of this report has been served upon all jurisdictional customers, interested state regulatory agencies, and all parties on the service list compiled by the Secretary in this proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.211 of the Commission's Rules of Practice and Procedure. All such protests must be filed on or before March 6, 1996. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

*Secretary.*

[FR Doc. 96-5072 Filed 3-4-96; 8:45 am]

BILLING CODE 6717-01-M

**[Docket No. SA96-2-000]**

**Teco Pipeline Company; Notice of  
Petition for Adjustment**

February 28, 1996.

Take notice that on January 17, 1996, Teco Pipeline Company (Teco) filed pursuant to section 502(C) of the Natural Gas Policy Act of 1978 (NGPA), a petition for adjustment from Section 285.123(b)(1)(ii) of the Commission's Regulations to permit Teco to use its tariff on file with the Railroad Commission of Texas (TRC), for suspendable firm and interruptible transportation services performed pursuant to NGPA Section 311.

In support of its petition, Teco states that it provides intrastate transportation service within the State of Texas, and is a gas utility subject to the jurisdiction of the TRC. Teco states that it will in the future perform transportation services pursuant to NGPA Section 311(a)(2) on behalf of interstate pipeline companies and/or local distribution companies served by interstate pipeline companies. It is anticipated that its system is or will soon be connected to the interstate facilities of Texas Eastern Transmission Corporation, Trunkline Gas Company, Tennessee Gas Pipeline Company, and Transcontinental Gas Pipeline Corporation. Teco will transport gas under Section 311(a)(2) pursuant to negotiated agreements, at rates not

greater than those for comparable intrastate service in its tariffs on file with the TRC. Teco at present has on file with the TRC a tariff which provides for certain intrastate firm and interruptible transportation services.

The regulations applicable to this proceeding are found in Subpart K of the Commission's Rules of Practice and Procedure. Any person desiring to participate in this rate proceeding must file a motion to intervene in accordance with Sections 385.211 and 385.214 of the Commission's Rules of Practice and Procedures. All motions must be filed with the Secretary of the Commission within 15 days after publication of this notice in the Federal Register. The petition for adjustment is on file with the Commission and is available for public inspection.

Lois D. Cashell,  
Secretary.

[FR Doc. 96-5069 Filed 3-4-96; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP96-211-000]

**Tennessee Gas Pipeline Company;  
Notice of Request Under Blanket  
Authorization**

February 28, 1996.

Take notice that on February 26, 1996, Tennessee Gas Pipeline Company (Tennessee), P.O. 2511, Houston, Texas 77252, filed in Docket No. CP96-211-000 a request pursuant to Sections 157.205 and 157.216 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.216) for authorization to abandon 3 sales meters along Tennessee's right-of-way in Wharton, Victoria and Jackson Counties, Texas, under Tennessee's blanket certificate issued in Docket No. CP82-413-000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Tennessee proposes to abandon the 3 meters, which were used for irrigation of rice farms, because they are no longer required by the customers and no gas is flowing through them. It is stated that Tennessee would abandon the meters, related value assemblies and all above-ground appurtenant facilities by removal and dispose of the material as scrap. It is asserted that the meters were installed in the 1950's and 1960's and that Tennessee's contracts for sales to the customers have all been terminated. Tennessee has provided letters from the three customers agreeing to the proposed abandonments.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,  
Secretary.

[FR Doc. 96-5074 Filed 3-4-96; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP94-423-004]

**Texas Gas Transmission Corporation;  
Notice of Proposed Changes in FERC  
Gas Tariff**

February 28, 1996.

Take notice that on February 23, 1996, Texas Gas Transmission Corporation (Texas Gas) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1 and Original Volume No. 2, the revised tariff sheets contained in Appendix A to become effective on the dates indicated.

Texas Gas states that this filing is made to comply with the provisions identified in the letter order which approved the Stipulation and Agreement in Docket No. RP94-423 issued February 20, 1996. Texas Gas intends to implement the provisions of the settlement in the referenced docket.

Texas Gas states that copies of the filing have been served upon Texas Gas's jurisdictional customers, all parties on the Commission's official service list in this proceeding, interested state commissions, and the FERC Staff.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the

Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,  
Secretary.

[FR Doc. 96-5071 Filed 3-4-96; 8:45 am]

BILLING CODE 6717-01-M

**Appendix A—Texas Gas Transmission  
Corporation**

*FERC Gas Tariff First Revised Volume No. 1*

Tariff Sheets Effective April 1, 1995

Substitute Third Revised Sheet No. 1

Substitute First Revised Sheet No. 9

Second Substitute Eighth Revised Sheet No. 10

Second Substitute Fifth Revised Sheet No. 11

Second Substitute Original Sheet No. 11A

Second Substitute Tenth Revised Sheet No. 12

Substitute Second Revised Sheet No. 12A

Second Substitute Third Revised Sheet No. 13

Second Substitute Second Revised Sheet No. 15

Second Substitute Second Revised Sheet No. 16

Substitute Second Revised Sheet No. 17

Substitute Fifth Revised Sheet No. 18

Second Substitute First Revised Sheet No. 122

Original Sheet No. 122A

Second Revised Sheet No. 145

Third Revised Sheet No. 207

Second Revised Sheet No. 208

First Revised Sheet No. 209

Third Revised Sheet No. 235

Second Revised Sheet No. 236

Tariff Sheets Effective June 1, 1995

Substitute Ninth Revised Sheet No. 10

Substitute Sixth Revised Sheet No. 11

Substitute First Revised Sheet No. 11A

Substitute Eleventh Revised Sheet No. 12

Tariff Sheets Effective September 1, 1995

Substitute Tenth Revised Sheet No. 10

Substitute Seventh Revised Sheet No. 11

Substitute Second Revised Sheet No. 11A

Substitute Twelfth Revised Sheet No. 12

Tariff Sheets Effective October 1, 1995

Substitute Eleventh Revised Sheet No. 10

Substitute Eighth Revised Sheet No. 11

Substitute Third Revised Sheet No. 11A

Substitute Thirteenth Revised Sheet No. 12

Substitute Fourth Revised Sheet No. 13

Tariff Sheets Effective November 1, 1995

Substitute Twelfth Revised Sheet No. 10

Substitute Ninth Revised Sheet No. 11

Substitute Fourth Revised Sheet No. 11A

Substitute Fourteenth Revised Sheet No. 12

Tariff Sheets Effective January 1, 1996

Substitute Thirteenth Revised Sheet No. 10

Substitute Tenth Revised Sheet No. 11

Substitute Fifth Revised Sheet No. 11A

Substitute Fifteenth Revised Sheet No. 12

Substitute Fifth Revised Sheet No. 13

Tariff Sheets Effective February 1, 1996

Substitute Fourteenth Revised Sheet No. 10

Substitute Eleventh Revised Sheet No. 11

Substitute Sixth Revised Sheet No. 11A

Substitute Third Revised Sheet No. 15

Substitute Third Revised Sheet No. 16

Tariff Sheets Effective March 1, 1996

Substitute Twelfth Revised Sheet No. 11

Substitute Seventh Revised Sheet No. 11A

Substitute Sixteenth Revised Sheet No. 12

Substitute Fourth Revised Sheet No. 16

Substitute Third Revised Sheet No. 17

*FPC Gas Tariff Original Volume No. 2*

Tariff Sheets Effective April 1, 1996

Substitute Nineteenth Revised Sheet No. 82

Substitute Twentieth Revised Sheet No. 547

Substitute Twenty-second Revised Sheet No. 982

Substitute Twentieth Revised Sheet No. 1005

Substitute Fourteenth Revised Sheet No. 1085

[FR Doc. 96-5071 Filed 3-4-96; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP96-206-000]

### **Transcontinental Gas Pipe Line Corporation; Notice of Application**

February 28, 1996.

Take notice that on February 12, 1996, Transcontinental Gas Pipe Line Corporation (Transco), P.O. Box 1396, Houston, Texas 77251, filed an application pursuant to Section 7(b) of the Natural Gas Act, for authority (1) To abandon by transfer to Williams Gas Processing-Gulf Coast (WGP), its affiliate, certain onshore and offshore certificated, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Transco states that as part of an ongoing corporate-wide restructuring of the Williams Companies, Inc. (Williams) with the objective of separating all gathering facilities from the jurisdictional transmission companies, Transco seeks to spin down to WGP all its onshore and offshore facilities which are used primarily for the purpose of gathering. It is indicated that WGP is organized as a separate, stand-alone company independent of the interstate pipeline affiliates and that the focus of its business is providing competitive unbundled gathering services.

Transco proposes to abandon two onshore systems, five offshore systems, and other miscellaneous onshore and offshore stub facilities. The onshore systems are The Tilden/McMullen Gathering System, which includes facilities in Frio, La Salle, McMullen, Atascosa, Live Oak, Bee, San Patricio, Goliad, Victoria, De Witt, Jackson, and Wharton Counties, Texas and the Kings Ranch Plant Gas Gathering System, which includes facilities in Hidalgo, Starr, Willacy, Brooks, Duval, Jim Wells, and Kleberg Counties, Texas. The offshore systems are the North Padre

Island Gathering System, the Central Texas Gathering System, and the North High Island/West Cameron Gathering System in offshore Texas and the Central Louisiana and Southeast Louisiana Gathering Systems in offshore Louisiana. In addition, Transco proposes to abandon certain miscellaneous offshore and onshore facilities, most of which are non-contiguous to Transco's system and connect instead with third-party pipelines. Transco proposes to abandon the facilities at net book value, which as of December 31, 1995, was approximately \$230,423,155.

Transco states that WGP has made a related filing in Docket No. CP96-207-000, requesting a declaratory order finding that the facilities which it will acquire will not be subject to the Commission's jurisdiction.

Any person desiring to be heard or to make any protest with reference to said application should on or before March 20, 1996, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that approval for the proposed abandonment is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be

unnecessary for Transco to appear or be represented at the hearing.

Lois D. Cashell,

*Secretary.*

[FR Doc. 96-5076 Filed 3-4-96; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP96-207-000]

### **Williams Gas Processing—Gulf Coast Company, L.P.; Notice of Petition for Declaratory Order**

February 28, 1996.

Take Notice that on February 21, 1996, Williams Gas Processing—Gulf Coast Company, L.P. (WGP), P.O. Box 1396, Houston, Texas 77251, filed a petition for declaratory order in Docket No. CP96-207-000, requesting that the Commission declare that WGP's proposed acquisition, ownership, and operation of certain onshore and offshore natural gas gathering systems and other facilities currently owned by Transcontinental Gas Pipe Line Corporation (Transco) would not subject WGP or any portion of its facilities, rates, or services to the jurisdiction of the Commission under the Natural Gas Act (NGA), all as more fully set forth in the petition which is on file with the Commission and open to public inspection.

WGP seeks a declaratory order finding that:

- The facilities described in its petition that WGP wishes to acquire from Panhandle will be gathering facilities exempt from the Commission's jurisdiction pursuant to Section 1(b) of the Natural Gas Act;
- WGP will not be a "natural gas company" pursuant to Section 2 of the Natural Gas Act by virtue of its proposed acquisition, ownership, and operation of such facilities;
- The gathering services to be performed by WGP will be non-jurisdictional gathering services exempt from the Commission's jurisdiction under Section 1(b) of the Natural Gas Act; and
- WGP's rates, and charges for gathering services will not be subject to the Commission's jurisdiction pursuant to Sections 4 and 5 of the Natural Gas Act.

WGP states that it is a wholly-owned subsidiary of The Williams Companies, Inc. (Williams). WGP is organized as a separate, stand-alone company independent of the interstate pipeline affiliates and that the focus of its business is providing competitive unbundled gathering services.

WGP indicates that it would acquire facilities directly from Transco

including gathering systems in onshore Texas, Louisiana, New Mexico, Oklahoma, and Mississippi, and in the adjacent offshore state waters and adjacent Outer Continental Shelf. Specifically, WGP would acquire two onshore systems, five offshore systems, and other miscellaneous onshore and offshore stub facilities. The onshore systems are The Tilden/McMullen Gathering System, which includes facilities in Frio, La Salle, McMullen, Atascosa, Live Oak, Bee, San Patricio, Goliad, Victoria, De Witt, Jackson, and Wharton Counties, Texas and the Kings Ranch Plant Gas Gathering System, which includes facilities in Hidalgo, Starr, Willacy, Brooks, Duval, Jim Wells, and Kleberg Counties, Texas. The offshore systems are the North Padre Island Gathering System, the Central Texas Gathering System, and the North High Island/West Cameron Gathering System in offshore Texas and the Central Louisiana and Southeast Louisiana Gathering Systems in offshore Louisiana. In addition, WGP will acquire certain miscellaneous offshore and onshore facilities, most of which are non-contiguous to Transco's system and connect instead with third-party pipelines. WGP notes that Transco has filed a related application in Docket No. CP96-206-000 requesting authority pursuant to Section 7(b) to abandon such facilities.

WGP states that it has initiated discussions and negotiations for post-abandonment gathering agreements with many of Transco's existing shippers and intends to negotiate with all existing customers. In the event WGP is unable to finalize negotiated agreements with all existing shippers, WGP asserts that it will ensure continuity of service for existing shippers in the manner required by the Commission.

It is argued that the facilities to be acquired by WGP meet the physical and non-physical criteria for determining gathering as set forth in *Farmland Industries, Inc.*, 23 FERC ¶ 61,063 (1983), as modified by subsequent Commission orders. WGP further argues that the offshore facilities it will acquire qualify as gathering in accordance with the "modified primary function test" as set forth in *Amerada Hess Corp. et al.*, 52 FERC ¶ 61,268 (1990).

Any person desiring to be heard or to make any protest with reference to said petition should on or before March 20, 1996, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211). All protests filed

with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Lois D. Cashell,

Secretary.

[FR Doc. 96-5075 Filed 3-4-96; 8:45 am]

BILLING CODE 6717-01-M

**[Docket No. ER94-389-006, et al.]**

**North American Energy Conservation et al.; Electric Rate and Corporate Regulation Filings**

February 27, 1996.

Take notice that the following filings have been made with the Commission:

1. Tenaska Power Services Company Energy Resource Marketing, Inc., and Phibro Inc.

[Docket Nos. ER94-389-006, ER94-1580-005, ER95-430-004 (not consolidated)]

Take notice that the following informational filings have been made with the Commission and are on file and available for inspection and copying in the Commission's Public Reference Room:

On January 29, 1996, Tenaska Power Services Company filed certain information as required by the Commission's May 26, 1994 order in Docket No. ER94-389-000.

On February 21, 1996, Energy Resource Marketing, Inc. filed certain information as required by the Commission's September 30, 1994 order in Docket No. ER94-1580-000.

On February 22, 1996, Phibro filed certain information as required by the Commission's June 9, 1995 order in Docket No. ER95-430-000.

2. Arkansas Power & Light Company

[Docket No. ER95-711-001]

Take notice that on February 15, 1996, Arkansas Power & Light Company tendered for filing its compliance filing in the above-referenced docket.

*Comment date:* March 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

3. Dartmouth Power Associates Partnership

[Docket No. ER96-149-001]

Take notice that on January 31, 1996, Dartmouth Power Associates Partnership tendered for filing a revised version of FERC Rate Schedule No. 2 for

the open-ended marketing of electricity at market-based rates.

*Comment date:* March 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

4. Cinergy Services, Inc.

[Docket No. ER96-409-001]

Take notice that on February 21, 1996, Cinergy Services, Inc. tendered for filing its refund report in the above-referenced docket.

*Comment date:* March 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

5. Dayton Power & Light Company

[Docket No. ER96-708-000]

Take notice that on February 21, 1996, Dayton Power & Light Company tendered for filing an amendment in the above-referenced docket.

*Comment date:* March 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

6. Maine Public Service Company

[Docket No. ER96-727-000]

Take notice that on February 15, 1996, Maine Public Service Company tendered for filing revised Appendix B to replace Appendix B filed December 29, 1995.

*Comment date:* March 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

7. Public Service Electric and Gas Company

[Docket No. ER96-952-000]

Take notice that on February 21, 1996, Public Service Electric and Gas Company tendered for filing an amendment in the above-referenced docket.

*Comment date:* March 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

8. Kentucky Utilities Company

[Docket No. ER96-1067-000]

Take notice that on February 13, 1996, Kentucky Utilities Company tendered for filing the first revisions of Appendix D to Kentucky Utilities Company's Transmission Service Tariff.

*Comment date:* March 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

9. Cleveland Electric Illuminating Company

[Docket No. ER96-1073-000]

Take notice that on February 15, 1996, Cleveland Electric Illuminating Company tendered for filing Service Agreements with Koch Power Services, Inc., CNG Power Services Corporation,

Louis Dreyfus Electric Power, Inc., Enron Power Marketing, Inc., Coastal Electric Services Company, Catex Vitol Electric, L.L.C., Noram Energy Services, Inc., Midcon Power Services Corp., and Citizens Lehman Power Sales.

*Comment date:* March 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

10. South Carolina Electric & Company  
[Docket No. ER96-1085-000]

Take notice that on February 20, 1996, SCANA Energy Marketing, Inc., tendered for filing additional material to the February 16, 1996, filing in the above-referenced docket.

*Comment date:* March 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

11. Texas Utilities Electric Company  
[Docket No. ER96-1087-000]

Take notice that on February 16, 1996, Texas Utilities Electric Company (TU Electric) tendered for filing amendments to the transmission service agreements (TSA's) with Delhi Energy Services, Inc. and Sonat Power Marketing Inc. that were originally filed herein on January 8, 1996.

TU Electric requests an effective date for the TSA's that will permit them to become effective on or before the service commencement date under the TSA's. Accordingly, TU Electric seeks waiver of the Commission's notice requirements. Copies of the filing were served on Delhi Energy Services, Inc. and Sonat Power Marketing Inc., as well as the Public Utility Commission of Texas.

*Comment date:* March 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

12. Entergy Services, Inc.

[Docket No. ER96-1112-000]

Take notice that on February 20, 1996, Entergy Services, Inc. (Entergy Services), on behalf of Arkansas Power & Light Company, Gulf States Utilities Company, Louisiana Power & Light Company, Mississippi Power & Light Company, and New Orleans Public Service Inc. (Entergy Operating Companies), tendered for filing a Second Amendment to the Non-Firm Transmission Service Agreement (Amendment) between Entergy Services, Inc. and NorAm Energy Services. Entergy Services states that the Amendment extends the effective date of Non-Firm Transmission Service Agreement.

*Comment date:* March 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

13. Kentucky Utilities Company

[Docket No. ER96-1113-000]

Take notice that on February 20, 1996, Kentucky Utilities Company (KU), tendered for filing an Amendment to the Interconnection Agreement between KU and the Big Rivers Electric Corporation. The filing provides for establishment of a new interconnection point at KU's Green River Power Plant 161 KV Substation near Central City, Kentucky. The Amendment also establishes an additional service schedule for Transmission Losses and a new contract termination provision. The Agreement between the parties dated September 1, 1989, which is on file with this Commission, Company Rate Schedule FERC No. 201, provides for establishing additional interconnection points and related amendments as needs arise.

Company states that copies of the filing have been sent to Big Rivers Electric Corporation, the Public Service Commission of Kentucky and the Virginia State Corporation Commission.

*Comment date:* March 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

14. Entergy Services, Inc.

[Docket No. ER96-1114-000]

Take notice that on February 20, 1996, Entergy Services, Inc. (Entergy), on behalf of Gulf States Utilities Company (GSU) and Louisiana Power & Light Company (LP&L), tendered for filing a supplement to the Power Interconnection Agreement between GSU and Louisiana Energy and Power Authority (LEPA), GSU Rate Schedule No. 136, dated November 15, 1982, and the Electric System Interconnection Agreement between LP&L and LEPA, LP&L Rate Schedule No. 72, dated October 1, 1982.

*Comment date:* March 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

15. Entergy Services, Inc.

[Docket No. ER96-1115-000]

Take notice that on February 20, 1996, Entergy Services, Inc. (Entergy Services), on behalf of Arkansas Power & Light Company, Gulf States Utilities Company, Louisiana Power & Light Company, Mississippi Power & Light Company, and New Orleans Public Service Inc. (Entergy Operating Companies), tendered for filing a Second Amendment to the Non-Firm Transmission Service Agreement (Amendment) between Entergy Services, Inc. and Noram Energy Services. Entergy Services states that the Amendment extends the effective date

of Non-Firm Transmission Service Agreement.

*Comment date:* March 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

16. Entergy Services, Inc.

[Docket No. ER96-1116-000]

Take notice that on February 20, 1996, Entergy Services, Inc. (Entergy Services), on behalf of the Arkansas Power & Light Company (AP&L) tendered for filing the Twenty-Fourth Amendment to the Power Coordination, Interchange and Transmission Service Agreement between Entergy Services, Inc. (Entergy Services), acting as agent for the Arkansas Power & Light Company (AP&L) and the Arkansas Electric Cooperative Corporation (AECC), dated June 27, 1977, which is on file with the Commission as AP&L Rate Schedule FERC No. 82. The Amendment changes the transmission and distribution service rate formulas currently in effect for AECC to the corresponding rate formulas currently in effect for AP&L's other formula rate customers. Conforming the AECC rate formulas will not result in any change in AP&L's charges to AECC for transmission and distribution service.

*Comment date:* March 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

17. Consolidated Edison Company of New York, Inc.

[Docket No. ER96-1117-000]

Take notice that on February 20, 1996, Consolidated Edison Company of New York, Inc. ("Con Edison") tendered for filing an agreement with Virginia Electric & Power Company ("VPC") to provide for the sale of energy and capacity. For energy the ceiling rate is 100 percent of the incremental energy cost plus up to 10 percent of the SIC (where such 10 percent is limited to 1 mill per KWhr when the SIC in the hour reflects a purchased power resource). The ceiling rate for capacity is \$7.70 per megawatt hour.

Con Edison states that a copy of this filing has been served by mail upon VPC.

*Comment date:* March 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

18. Kansas City Power & Light Company

[Docket No. ER96-1118-000]

Take notice that on February 20, 1996, Kansas City Power & Light Company (KCPL), tendered for filing a Service Agreement dated March 1, 1996, between KCPL and Illinois Power



Company (IPC). KCPL proposes an effective date of March 1, 1996, and requests waiver of the Commission's notice requirement. This Agreement provides for the rates and charges for Non-Firm Transmission Service between KCPL and IPC.

In its filing, KCPL states that the rates included in the above-mentioned Service Agreement are KCPL's rates and charges which were conditionally accepted for filing by the Commission in Docket No. ER94-1045-000.

*Comment date:* March 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

#### 19. Kibler Energy Ltd.

[Docket No. ER96-1119-000]

Take notice that on February 20, 1996, Kibler Energy Ltd. tendered for filing a Petition for Order Accepting Initial Rate Schedule for Filing, Determining Rates to be Just and Reasonable, Waving Regulations and Granting Preapproval.

*Comment date:* March 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

#### 20. Pennsylvania Power & Light Company

[Docket No. ER96-1120-000]

Take notice that on February 20, 1996, Pennsylvania Power & Light Company (PP&L), tendered for filing with the Federal Energy Regulatory Commission two Service Agreements (the Agreements) between PP&L and Southern Energy Marketing, Inc., dated January 12, 1996; and (2) US Gen Power Services, L.P., dated January 26, 1996.

The Agreements supplement a Short Term Capacity and Energy Sales umbrella tariff approved by the Commission in Docket No. ER95-782-000 on June 21, 1995.

In accordance with the policy announced in *Prior Notice and Filing Requirements Under Part II of the Federal Power Act*, 64 FERC ¶ 61,139, *clarified and reh'g granted in part and denied in part*, 65 FERC ¶ 61,081 (1993), PP&L requests the Commission to make the Agreement effective as of February 20, 1996, because service will be provided under an umbrella tariff and each service agreement is filed within 30 days after the commencement of service. In accordance with 18 C.F.R. 35.11, PP&L has requested waiver of the sixty-day notice period in 18 C.F.R. 35.2(e). PP&L has also requested waiver of certain filing requirements for information previously filed with the Commission in Docket No. ER95-782-000.

PP&L states that a copy of its filing was provided to the customers involved

and to the Pennsylvania Public Utility Commission.

*Comment date:* March 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

#### 21. Duke/Louis Dreyfus Energy Services (New England) L.L.C.

[Docket No. ER96-1121-000]

Take notice that on February 20, 1996, Duke/Louis Dreyfus Energy Services (New England) L.L.C. (the Applicant), tendered for filing its FERC Electric Rate Schedule No. 1 to be effective April 21, 1996, and requested that the Commission waive certain of its regulations and grant blanket approval with respect to the issuance of securities and assumption of obligations or liabilities.

The Applicant was formed by Duke/Louis Dreyfus L.L.C. and EUA Energy Services, Inc.

*Comment date:* March 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

#### 22. NFR Power, Inc.

[Docket No. ER96-1122-000]

Take notice that on February 21, 1996, NFR Power, Inc. (NFR Power), 478 Main Street, Buffalo, New York 14202, petitioned the Commission for acceptance of NFR Power Rate Schedule FERC No. 1; the granting of certain blanket approvals, including the authority to sell electricity at market-based rates; and the waiver of certain Commission Regulations. NFR Power is a subsidiary of National Fuel Gas Company, an integrated natural gas company.

*Comment date:* March 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

#### 23. Cinergy Services, Inc.

[Docket No. ER96-1123-000]

Take notice that on February 21, 1996, Cinergy Services, Inc. (Cinergy), tendered for filing on behalf of its operating companies, The Cincinnati Gas & Electric Company (CG&E) and PSI Energy, Inc. (PSI), an Electric Sales Agreement, dated February 1, 1996, between Cinergy, CG&E, PSI and Missouri Public Service (MPS).

The Electric Sales Agreement provides for the following service between Cinergy and MPS.

1. Service Schedule A—Emergency Service
2. Service Schedule B—System Energy
3. Service Schedule C—Negotiated Capacity and Energy

Cinergy and MPS have requested an effective date of March 1, 1996.

Copies of the filing were served on Missouri Public Service Commission,

the Kentucky Public Service Commission, Public Utilities Commission of Ohio and the Indiana Utility Regulatory Commission.

*Comment date:* March 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

#### 24. Florida Power & Light Company

[Docket No. TX93-4-005]

Take notice that on February 21, 1996, Florida Power & Light Company tendered for filing its compliance filing in the above-referenced docket.

*Comment date:* March 12, 1996, in accordance with Standard Paragraph E at the end of this notice.

#### Standard Paragraph

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

*Secretary.*

[FR Doc. 96-5003 Filed 3-4-96; 8:45 am]

BILLING CODE 6717-01-P

#### [Project No. 3574-004]

#### Continental Hydro Corp. and Gas Company; Notice of Availability of Environmental Assessment

February 28, 1996.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission's) Regulations, 18 CFR Part 380 (Order No. 486, 52 FR 47897), the Office of Hydropower Licensing has reviewed the application for a license for the Tiber Dam Hydroelectric Project No. 3574-004, located at the Bureau of Reclamation's existing Tiber Dam and Lake Elwell, on the Marias River in Liberty County, Montana. The Commission has prepared a draft Environmental Assessment (EA) for the project. The draft EA contains the Commission staff's analysis of the



potential future environmental impacts of the project and has concluded that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

Copies of the EA are available for review in the Public Reference Room, Room 2A, of the Commission's offices at 888 First Street, N.E., Washington, D.C. 20426.

Any comments should be filed within 30 days from the date of this notice and should be addressed to Lois D. Cashell, Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426. For further information, contact Surender M. Yepuri, Environmental Coordinator, at (202) 219-3847.

Lois D. Cashell,  
Secretary.

[FR Doc. 96-5068 Filed 3-4-96; 8:45 am]

BILLING CODE 6717-01-M

#### [Project No. 2310-073 California]

#### Pacific Gas & Electric Co.; Notice of Availability of Environmental Assessment

February 28, 1996.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission's) Regulations, 18 CFR Part 380 (Order No. 486, 52 FR 47897), the Commission's Office of Hydropower Licensing has reviewed a non-capacity related amendment of license for the Drum Spaulding Hydroelectric Project, No. 2310-073. The Drum Spaulding Project is located on the Bear, South Yuba, and North Fork American Rivers in Placer and Nevada Counties, California. The plan is for a revised recreation plan for the project. An Environmental Assessment (EA) was prepared for the plan. The EA finds that approving the plan would not constitute a major federal action significantly affecting the quality of the human environment.

Copies of the EA are available for review in the Public Reference Room, Room 2A, of the Commission's offices at 888 First Street, N.E., Washington, D.C. 20426.

Lois D. Cashell,  
Secretary.

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[Docket No. RM96-5-000]

#### Gas Pipeline Facilities and Services on the Outer Continental Shelf—Issues Related to the Commission's Jurisdiction Under the Natural Gas Act and the Outer Continental Shelf Lands Act; Statement of Policy

Issued February 28, 1996.

#### I. Introduction

In this docket, the Commission has been exploring the issue of the application of its jurisdiction under the Natural Gas Act (NGA)<sup>1</sup> and the Outer Continental Shelf Lands Act (OCSLA) over natural gas facilities and services on the Outer Continental Shelf (OCS).<sup>2</sup> In response to several recent requests that the Commission declare existing certificated offshore systems<sup>3</sup> and proposed offshore facilities in the Gulf of Mexico<sup>4</sup> to be exempt gathering facilities, and in view of increases in

<sup>1</sup> Section 1(b) of the NGA grants the Commission regulatory jurisdiction over "the transportation of natural gas in interstate commerce" and "the sale in interstate commerce of natural gas for resale." At the same time, section 1(b) exempts from the NGA's coverage "the production or gathering of natural gas." Thus, section 1(b) first grants to the Commission broad plenary authority to regulate the business of transporting and of wholesaling natural gas moving in interstate commerce. Secondly, section 1(b) removes from that plenary grant of federal jurisdiction those aspects of natural gas regulation which are the proper subject of state regulation.

<sup>2</sup> Generally, sections 5(e) and 5(f)(1) of the OCSLA give the Commission certain responsibilities and authorizations to ensure that natural gas pipelines on the OCS transport for non-owner shippers in a nondiscriminatory manner and operate in accordance with certain competitive principles. Section 5(e) of the OCSLA requires pipelines to transport natural gas produced from the OCS "without discrimination" and in such "proportionate amounts" as the Commission, in consultation with the Secretary of Energy, determines to be reasonable. In addition, section 5(f)(1) of the OCSLA requires pipelines transporting gas on or across the OCS to adhere to certain "competitive principles." These "competitive principles" include a requirement that the pipeline must provide "open and nondiscriminatory access to both owner and nonowner shippers." The applicability of the provisions of sections 5(e) and 5(f)(1) is not restricted to interstate pipelines that are subject to the Commission's NGA jurisdiction.

The only pipelines that may be exempt from the Commission's authority under the OCSLA are certain "feeder lines," which are defined in section 5(f)(2) of the OCSLA as a pipeline that feeds into a facility where oil and gas are "first collected" or a facility where oil and gas are "first separated, dehydrated, or otherwise processed." These "feeder lines" may only be exempted from the requirements of the OCSLA by order of the Commission.

<sup>3</sup> See Sea Robin Pipeline Company (Sea Robin), 71 FERC ¶ 61,351 (1995) (denying request for declaration of gathering status), *reh'g pending*; Enron Gulf Coast Gathering L.P., Docket No. CP95-516-000; and, Venice Gathering Company, Docket No. CP95-202-000.

<sup>4</sup> See Shell Gas Pipeline Company (SGPC), Docket No. CP96-9-000 (issued contemporaneously with this policy statement) and SGPC, Docket No. CP96-113-000.

successful offshore exploration and development activities, the Commission has elected to review issues concerning the status, scope, and effect of its regulation of gathering and transportation on the OCS. In view of the importance of current OCS production,<sup>5</sup> and its potential as a source of new production, the Commission seeks in this proceeding to assure that regulatory policies do not impede or distort development activities on the OCS.

The Commission solicited comments on the operational considerations pertaining to OCS exploration and development activities, and the legal and policy issues implicated in either maintaining or departing from present policy.<sup>6</sup> Thirty-five responses were submitted by representatives of all segments of the industry.<sup>7</sup> The Commission has reviewed these comments and will clarify its regulation of OCS facilities and services, as discussed below.

#### II. Background

In 1989, in response to the decision in *EP Operating Co. v. FERC (EP Operating)*<sup>8</sup>—which reversed a Commission determination that a 16-inch diameter, 51-mile long pipeline connecting an OCS production platform to an offshore processing plant was a jurisdictional transportation facility—the Commission set upon a review of its gathering policy. The purpose of that review was to assess the impact of *EP Operating* as well as the continuing viability and relevance of the "primary function" test, which at that time was the Commission's preferred methodology for determining the jurisdictional status of gas pipeline facilities.<sup>9</sup> That review culminated in

<sup>5</sup> The Gulf of Mexico is the largest single domestic source of natural gas production, currently representing 27 percent of the lower 48 states' total dry gas production and 17 percent of proven reserves. Energy Information Administration, 1994 Annual Report, U.S. Crude Oil, Natural Gas, and Natural Gas Liquids Reserves, Table 8 at 28 and Table 9 at 31 (October 1995).

<sup>6</sup> See Notice of Inquiry into Jurisdictional Issues Respecting Natural Gas Pipeline Facilities and Services on the Outer Continental Shelf (NOI), 73 FERC ¶ 61,227 (1995).

<sup>7</sup> Four parties filed comments out-of-time, which for good cause shown, we accept. Minerals Management Service and Williams Field Services filed supplemental comments and OCS Producers filed reply comments. A list of the commenters is included as an appendix to this policy statement.

<sup>8</sup> 876 F.2d 46 (5th Cir. 1989).

<sup>9</sup> The "primary function" test was articulated in *Farmland Industries, Inc. (Farmland)*, 23 FERC ¶ 61,063 (1983). In *Farmland* the Commission enumerated several physical and geographic criteria to be included in the analysis for determining whether the primary function of a facility is the

Continued

the Commission's articulation and application of the "modified primary function" test in *Amerada Hess Corporation*, (*Amerada Hess I*).<sup>10</sup>

*Amerada Hess I* explained that because of recent advances in engineering and available technology, offshore drilling operations were moving further offshore and further from existing interstate pipeline interconnections. Accordingly, a relatively long pipeline on the OCS may be consistent with a primary function of gathering or production whereas an onshore pipeline of similar length would not. Therefore, in applying the primary function test to offshore pipeline facilities, the Commission modified that test in order to apply, in effect, a sliding scale that would allow for the use of gathering pipelines of increasing lengths and diameters in correlation to the distance from shore and the water depth of the offshore production area. Specifically, when applying the *Farmland* criteria, the Commission stated that it would consider, especially for offshore facilities, the changing technical and geographic nature of exploration and production.

### III. The Notice of Inquiry

As explained in the NOI, the Commission has been prompted to reexamine its approach to regulating OCS facilities in view of the fact that several companies have filed, or indicated their intent to file, requests for exempt gathering status for proposed projects designed to bring gas onshore from significant, newly developed deep water reserves in the Gulf of Mexico. Additionally, there are pending requests to declare existing certificated offshore systems to be gathering, including Sea Robin's request for rehearing of the Commission's June 15, 1995 order denying gathering status for its offshore system. Accordingly, the NOI set out issues to be addressed by commenters regarding the need for continued NGA

transportation or the gathering or production of natural gas. These factors are: (1) the length and diameter of the line, (2) the extension of the facility beyond the central point in the field, (3) the lines' geographic configuration, (4) the location of compressors and processing plants, (5) the location of wells along all or part of the facility, and (6) the operating pressure of the line. The primary function test has been found by the Commission to be applicable to both onshore and offshore facilities. The criteria set out in *Farmland* were not intended to be all inclusive. The Commission has also considered nonphysical criteria such as the intended purpose, location, and operation of the facility, the general business activity of the owner of the facility, and whether the jurisdictional determination is consistent with the objectives of the NGA and the Natural Gas Policy Act of 1978 (NGPA).

<sup>10</sup> 52 FERC ¶ 61,268 (1990).

regulation of offshore facilities. The NOI contained a number of specific questions, among them whether the Commission should: continue to distinguish between gathering and transportation on the OCS; declare all OCS facilities to be gathering exempt from the Commission's jurisdiction under NGA section 1(b); issue a rule under the NGA declaring all OCS facilities to be jurisdictional transportation facilities; adopt a "light-handed" regulatory approach that relies on complaints of discriminatory access and/or the regulatory authority provided by the OCSLA; or, continue application of the modified primary function test on a case-by-case basis.

### IV. Comments<sup>11</sup>

The commenters overwhelmingly reject the suggestion that the Commission eliminate the distinction between transportation and gathering, maintaining that it is necessary, as a practical and legal matter, to continue to segregate facilities that perform primarily different functions.<sup>12</sup> Generally, interstate pipelines assert that regulation under the OCSLA is adequate given OCS competition and parties' recourse to a complaint proceeding; generally producers believe continued NGA rate regulation is necessary to protect against OCS interstate pipelines' market power.

Commenters maintain that a declaration that all OCS facilities are of one generic type would constitute a precipitous departure from the Commission's past practice of case-specific consideration, upset parties'

<sup>11</sup> Marathon Oil submitted a response requesting that the Commission establish a priority for casinghead gas. However, as Marathon Oil notes, this particular concern is "not included in the Commission's list of questions;" therefore, this policy statement does not address the merits of Marathon Oil's request. We note a similar proposal to provide a priority for casinghead gas was considered and rejected in Order Nos. 509 and 509-A. Interpretation of, and Regulation of the OCSLA Governing Transportation of Natural Gas by Interstate Natural Gas Pipelines on the OCS, 53 FR 50,925 (December 19, 1988), FERC Stats. & Regs., ¶ 30,842 at 31,290 (1988), on reh'g, 54 FR 8,301 (February 28, 1989), FERC Stats. & Regs., ¶ 30,848 at 31,347-48 (1989).

The State of Louisiana urged the Commission not to take any action that might extend federal regulation to include gathering activities in state waters which have traditionally been considered subject to regulation by the states. The Commission does not anticipate the clarification of its primary function test contained herein will affect the regulatory scheme now in effect offshore in state waters.

<sup>12</sup> Four parties—interstates Columbia, Natural, and Tennessee, and local distribution company (LDC) Brooklyn Union—argued for a blanket gathering declaration; the remaining thirty commenters seek to maintain, to one degree or another, the distinction between gathering and transportation, or else express no opinion.

reliance upon functional classifications in developing offshore reserves and accepting terms and conditions of service, and invite judicial reversal. Gatherers Leviathan and Tejas note that NGA section 1(b) specifically exempts gathering facilities from the Commission's NGA jurisdiction; thus, particularly in light of *EP Operating*, the Commission is without authority under the NGA to find all OCS facilities to be jurisdictional. OCS Producers<sup>13</sup> concur, and add that it would constitute an abdication of the Commission's regulatory responsibility under NGA section 1(b) to classify all OCS facilities as gathering. OCS Producers argue that pipeline systems, including facilities offshore, perform different functions, that the Commission's historical practice has been to recognize the different functions through application of a primary function test, and that courts have upheld this practice. OCS Producers also raise concerns about the Commission's need to regulate the rates charged by the pipelines. Producers Blue Dolphin Exploration and Energy Development assert that OCS pipelines possess market power and it is the Commission's responsibility under the NGA is to protect gas consumers from the exercise of such power.

The NOI sought comments on whether absent NGA regulation of OCS facilities or services, the Commission's regulatory authority under the OCSLA alone would be sufficient to protect the public interest, or would result in a regulatory gap.

Section 5(f)(1) of the OCSLA provides that pipelines must provide open and nondiscriminatory access. Parties recognize that the scope of the Commission's regulatory reach over gas gathering and transportation under the OCSLA is largely untested and differ in their interpretation of the extent and type of action the Commission might take to assure open and nondiscriminatory access. However, parties agree that the OCSLA does not provide for NGA-type cost-based rate regulation.

Interstate pipelines,<sup>14</sup> producer-owned pipelines, gatherers Leviathan,

<sup>13</sup> OCS Producers represents the interests of major producers of oil and gas on the OCS, and marketers, and/or shippers on OCS pipelines and consists of: Amerada Hess Corporation; Amoco Production Company and Amoco Energy Trading Corporation; Anadarko Petroleum Corporation; Ashland Exploration Inc.; Chevron U.S.A. Inc.; Conoco Inc.; Exxon Corporation; Marathon Oil Company; Meridian Oil Inc.; Mobile Natural Gas Inc.; Oryx Energy Company; OXY USA Inc.; Phillips Petroleum Company; Shell Offshore Inc.; Texaco Natural Gas Inc.; and, Union Pacific Fuels, Inc.

<sup>14</sup> Excepting Blue Dolphin Pipe Line, which argues that absent a legislative mandate, the

Tejas, and Williams Field Services, and LDC Brooklyn Union consider the Commission's authority under the OCSLA to be sufficient to protect the public interest.<sup>15</sup> These parties generally maintain that because of the competitive environment offshore, light-handed OCSLA oversight, coupled with a complaint procedure, can provide an adequate safeguard against the exercise of market power.<sup>16</sup> PanEnergy contends the Commission's authority under the OCSLA is broad enough to encompass establishing nondiscriminatory rates. These parties do not anticipate that reliance upon the OCSLA alone will produce a regulatory gap.

In contrast, producers<sup>17</sup> and industrial end users<sup>18</sup> are wary of relying solely on the OCSLA and what they view as a cumbersome complaint procedure. They contend that absent the Commission's NGA rate regulation, barriers to entry and a current lack of transportation alternatives leave OCS producers subject to OCS transportation pipelines' potential to exercise market power. For example, Energy Development states the OCSLA protects only access, but does not provide the Commission authority to regulate OCS transportation rates, and without rate regulation there is no effective check on the exercise of market power. Producers and end users predict that removing NGA rate regulation would result in a regulatory gap.<sup>19</sup>

Several commenters stress that the Commission may not opt to substitute OCSLA regulation for NGA regulation, since simultaneous regulation is mandated by statute.<sup>20</sup> Enserch, NGSA, and Texaco speculate that if the Commission were to rely solely on the OCSLA and remedial complaint

procedures, rate and litigation uncertainties would chill offshore exploration and development.

The NOI asked whether the Commission should, under a light-handed regulatory approach, distinguish between new and existing OCS pipelines. Most interstate<sup>21</sup> and gatherers<sup>22</sup> assert that a distinction between OCS facilities based on age would be inappropriate, unlawful, and place existing facilities which are subject to NGA rate regulation at a competitive disadvantage. However, interstate Koch, and producer Texaco, suggest that new facilities be presumed to be gathering, and thus eligible for light-handed regulation under the OCSLA. Tejas comments that new gathering lines will be less likely to exert market power than existing pipelines.

Some producers<sup>23</sup> argue that a lack of market power, not vintage, is the proper criteria to consider in distinguishing which facilities might appropriately be subject to light-handed regulation. OCS Producers accept that vintage might be considered as a factor when determining whether light-handed regulation is appropriate in a particular instance. Total Minatome urges that light-handed regulation apply only to production from OCS leases granted after promulgation of such regulation so as not to thwart the expectations upon which prior development was undertaken. Leviathan proposes to distinguish existing facilities which have customers who have relied on a certain level of regulation from new facilities which have customers with no such reliance.

The NOI requested comments on the option of allowing all rate regulation to end at any point that a pipeline and a non-affiliated shipper agree. INGAA and PanEnergy endorse the proposal. OCS Producers, Process Gas Consumers, Blue Dolphin Pipe Line, and Tejas disagree with this option. Tennessee asserts there should be no rate regulation behind the processing plant, regardless of agreement. Total Minatome claims this option is not needed, since pipelines can currently negotiate discounts with any customer and minimum rates are low enough to not inhibit freely negotiated rates. Leviathan also rejects this option and proposes market-based rates for new supply facilities 24 inches in diameter or less, light-handed rate regulation for new supply facilities greater than 24 inches in diameter, and

light-handed rate regulation (through a rate freeze and an inflation adjustment) for existing OCS facilities.

Several parties addressed particular concerns involving rates. Atlanta Gas, Brooklyn Union, and Natural argue that if the Commission were to declare existing OCS jurisdictional facilities to be gathering, then it should promptly require pipelines to revise their rates to exclude costs associated with their OCS facilities from their rates. Leviathan proposes an anti-cost-shifting limitation to prevent cross-subsidies between existing and new facilities by barring discount rate adjustments for jurisdictional purposes by a market area pipeline in setting downstream rates for downstream transportation of gas transportation on OCS facilities of that pipeline or its affiliates. Brooklyn Union claims a number of interstate pipelines have onshore or offshore points of aggregation, and that transportation facilities upstream of these pooling points provide the same function as OCS facilities; consequently, these facilities, like OCS facilities, should be subject only to light-handed regulation.

The NOI asked parties to consider the rationale for and consequences of declaring all offshore facilities to be either gathering or transportation. No party adopted the proposition that all OCS facilities be declared transportation. Columbia, Natural, Tennessee, and Brooklyn Union argued for a generic determination that all offshore facilities are gathering. CNG proposes a limited declaration of nonjurisdictional status for OCS pipelines owned by producers (or their affiliates) and used exclusively by the same producers (or their affiliates), claiming such facilities function as extensions of the production platforms to which they are connected. All other parties seek to maintain, to one degree or another, the distinction between gathering and transportation, or else express no opinion.

If the Commission did declare all offshore facilities gathering, Leviathan, Sea Robin, Tejas, and Tennessee suggest existing customers' expectations may be protected, as they have been onshore, through a default contract mechanism. Leviathan proposes a term that runs for the life of the currently connected reserves with an option to purchase gas supplies attached to competing offshore pipelines. Tennessee suggests a contract term of two years, and adds that issues relating to existing customers could be resolved in individual abandonment proceedings. Total Minatome proposes retaining the existing rate structure for current shippers for the life of production and providing that current

Commission cannot displace its NGA regulatory obligations by acting exclusively under the OCSLA.

<sup>15</sup> Tejas conditions its endorsement of OCSLA-only regulation upon the Commission's finding "that interstate transportation on the entire OCS is workably competitive and that no interstate pipelines have market power over OCS transportation."

<sup>16</sup> Leviathan would not rely entirely on complaints. Leviathan proposes to maintain cost-of-service based rates for existing OCS pipelines for three years, with annual inflation adjustments, and would similarly apply cost-based rates to new facilities exceeding 24 inches in diameter. Blue Dolphin Pipe Line is concerned about the administrative burden born by the complainant and the fact that relief will be, at best, prospective.

<sup>17</sup> OCS Producers, IPAA, NGSA, Blue Dolphin Exploration, CNG, Energy Development, Total Minatome, and Vastar.

<sup>18</sup> Process Gas Consumers and NGSA.

<sup>19</sup> OCS Producers, IPAA, NGSA, Blue Dolphin Exploration, Energy Development, Total Minatome, Process Gas Consumers, and NGSA.

<sup>20</sup> Blue Dolphin Exploration, Energy Development, CNG, IPAA, OCS Producers, NGSA, and Process Gas Consumers.

<sup>21</sup> INGAA, Columbia, Sea Robin, PanEnergy, and Tennessee.

<sup>22</sup> Centana and Williams Field Services.

<sup>23</sup> Blue Dolphin Exploration and IPAA.

shippers receive any lesser rate that might be negotiated by new shippers. PanEnergy rejects the need for a default contract, noting gathering facilities offshore remain subject to the Commission's OCSLA jurisdiction. Columbia, Enron, and PanEnergy believe that vigorous competition and the Commission's ability to remedy discrimination under the OCSLA will protect existing customers' expectations. Blue Dolphin Exploration states that the Commission should protect existing customers by (1) conditioning any declaration of gathering status for existing facilities owned by interstates or their affiliates upon divestiture of those facilities to a non-pipeline, non-pipeline affiliate party, and, (2) requiring interstate pipelines to divest all interests in offshore gathering facilities to unaffiliated, non-interstate owned or controlled third parties. OCS Producers contend that without NGA rate regulation, no uniform standard conditions could adequately protect historical customers.

As noted above, the vast majority of comments received reject the prospect of a blanket declaration and instead advocate continuing to distinguish between gathering and transportation on a case-by-case basis. However, while producers and industrial end users endorse a continued application of the Commission's current modified primary function test, other parties propose that that test be altered in various ways.

Interstate and producer-owned pipelines complain that nonjurisdictional gatherers enjoy competitive advantages over regulated transporters and urge the Commission to apply the primary function test in a manner that favors finding OCS facilities to be gathering. For example, INGAA asserts the Commission should continue with a case-specific analysis, but should "customize its analysis for offshore facilities," recognizing that size, ownership, and vintage are not necessarily determinative of gathering offshore, whereas the behind-the-plant location of many offshore lines demonstrates their "true gathering nature." Rather than relying exclusively on a bright-line physical test, Sea Robin urges the Commission to consider the commercial function of an OCS facility. ANR would eliminate ownership as a factor when considering the status of jurisdictional stand-alone OCS facilities. Williams Field Services maintains that gathering systems' facilities may extend beyond a processing plant to deliver into multiple transportation systems.

Enron and PanEnergy propose adopting a rebuttable presumption that all offshore facilities are gathering.

Hence, gathering status for new and existing facilities would be granted unless parties opposed demonstrate the facilities function primarily as transportation. Koch and Texaco would limit the presumption to new offshore facilities so as not to disturb the expectations of existing owners and customers. Texaco would also require that an existing jurisdictional pipeline seeking gathering status be evaluated in view of the technology employed at the time the facilities were constructed and be obliged to demonstrate that circumstances have changed since the facilities were initially classified.

On the other hand, producers and industrial end users generally urge the Commission to continue applying the primary function test without any change which would skew that test in favor of a gathering determination. OCS Producers, IPAA, NGSA, and Process Gas Consumers maintain there is no legal or policy basis for altering the Commission's present application of the modified primary function test. OCS Producers claim that revisions of the test such as elevating the behind-the-plant factor above all others, "would lead to the conclusion that virtually all pipeline facilities on the OCS are nonjurisdictional gathering." OCS Producers, Vastar, and Blue Dolphin Exploration endorse the outcome of the Commission's application of the primary function test in *Sea Robin*.

CNG would have the Commission disregard the behind-the-plant and central-point-in-the-field factors, and the facilities' geographic configuration and ownership, in favor of those factors deemed relevant to determining an offshore facility's core operation, namely: size, location of connecting platforms, operating pressures, and compression. According to CNG, pipelines with a single or serial attachment of supply sources serve as surrogate supply laterals and are likely to be gathering, whereas systems that generate economies of scale in aggregating multiple, scattered sources of supply are likely to be transportation.

Total Minatome considers offshore production platforms to function as the central point in a field, aggregating gas from different wells. Accordingly, Total Minatome views the large diameter lines that move gas from platforms as transportation lines, and proposes that the short, low-pressure lines linking multiple platforms be considered feeder lines under the OCSLA and gathering lines under the NGA.

Leviathan, a gatherer, proposes a novel jurisdictional test whereby new OCS system extensions of market area pipelines—i.e., expansions to reach new

production or attach additional OCS supplies—would be treated as jurisdictional transportation if the pipe diameters exceeded 24 inches. Market area pipelines' new supply pipe with a diameter of 24 inches or less would be treated as gathering. New jurisdictional production area facilities greater than 24 inches in diameter, including extensions of jurisdictional pipelines, would be treated as jurisdictional transportation facilities. Existing and new gathering facilities, including new OCS supply pipe with a diameter of 24 inches or less, would be presumed to be nonjurisdictional. Existing OCS transportation facilities would be treated as they have been historically.

#### V. Commission Response and OCS Policy

As stated in the NOI, the Commission has been presented with recent requests to clarify the jurisdictional status of OCS pipeline facilities. These facilities are an integral part of proposals to explore and develop natural gas reserves in deep water areas of the Gulf of Mexico and bring gas from such projects onshore for processing and delivery into the onshore interstate transportation grid. On the one hand, the Commission recognizes that such projects are expensive, and would not be undertaken in an atmosphere of regulatory uncertainty. We do not want to employ a policy that might impede exploration and development of these new areas. On the other hand, we are mindful of our obligations under the NGA to prevent the exercise of market power by companies that transport natural gas.

To strike a balance between these different objectives, we will retain our existing primary function test and clarify how we intend to apply that test for determining whether particular facilities constitute gathering facilities exempt from our jurisdiction under NGA section 1(b). We will add a new factor to our primary function test that will apply to facilities that are designed to collect gas produced in water depths of 200 meters or greater. Such facilities will be presumed to qualify as gathering facilities up to the point or points of potential connection with the interstate pipeline grid. From there on, the facilities will be evaluated under our existing primary function test and if found to be primarily transportation facilities, will be subject to our jurisdiction under NGA section 7.

We realize this statement of our gathering policy will require further refinement in that it leaves unresolved a number of questions that will have to be addressed in individual cases. For

instance, what constitutes a point of potential connection with the interstate pipeline grid may depend on individual circumstances. In *SGPC*, Docket No. CP96-9-000, which we are issuing contemporaneously with this policy statement, the platform and downstream stub lines interconnecting with Texas Eastern Transmission Corporation's interstate line six miles away are considered gathering. All facilities downstream of these are deemed to be transportation. To consider another example, the Viosca Knoll system (which predates this policy statement, but which we believe is consistent with it) was constructed in depths less than 200 meters, but was specifically designed to access new, deep water production. Viosca Knoll, a 20-inch diameter, 95-mile pipeline, was constructed roughly parallel to the edge of the Continental Shelf in a type of "header" configuration interconnecting with interstate pipelines at either end. The facility was declared to be gathering then and a similar project would qualify for a presumption of gathering under the policy we are adopting today.<sup>24</sup>

Despite the issues that will still need to be addressed in individual cases, we believe the above policy provides the necessary certainty for most new projects and fairly balances the concerns raised by the commenters in this proceeding. Many commenters, for instance, opposed any initiative that would effectively eliminate NGA regulation on the OCS and rely only on the OCSLA to provide a level playing field. Commenters pointed to reliance on the existing regulatory scheme for access to reasonably priced transportation and protection against market power by interstate pipelines. The policy adopted here would not upset that scheme. Existing interstate pipelines and gathering facilities would retain their status barring some change in circumstances, and new proposals for construction on the OCS would be considered under the current primary function test for gathering.

At a depth of roughly 200 meters, however, geographical and topographical changes on the sea floor make a rigid application of the modified primary function test undesirable. This is the point at which the Outer Continental Shelf drops off sharply to very deep waters. Of necessity, exploration past this point must rely on large, floating production platforms. The expense of exploring for and producing gas at these depths is considerably

greater than in shallower waters.<sup>25</sup> This depth also is consistent with the 200 meter depth specified in the Outer Continental Shelf Deep Water Royalty Relief Act, which provides royalty relief to encourage new oil and gas production in deep water lease blocks in the Gulf of Mexico. See P.L. 104-58, Title III, 43 USC § 1337 (1995).

There is little point in attempting to distinguish between new projects of this kind based on their physical features. Such deep water projects perform essentially the same function and they are all primarily engaged in production and gathering activities. We think the better approach is to consider all such facilities as production and gathering facilities up to the point where they duplicate or are in proximity to facilities that are established as transportation facilities; downstream of that point, we will determine the facilities' jurisdictional status based on our primary function test.

At present, there are a limited number of projects that produce from these depths, so there is no significant reliance by investors, producers, or shippers on an established regulatory scheme. Further, the companies who are sponsoring pending projects are large companies that intend to produce, gather, and transport their own gas and who appear less in need of regulatory protection than others closer to shore. As noted in the comments, these producers closer to shore have relied on regulated interstate pipelines to transport most, if not all, of their gas onshore and may be captive to these pipelines if Commission oversight were suddenly withdrawn. In sum, it is our view that under current circumstances the need for NGA regulation of deep water projects far offshore is significantly less than it is elsewhere.

Having said this, however, we note that where gas is destined for interstate commerce, there is necessarily a point at which the gathering or collection of the gas ends, and interstate transportation begins. The original primary function test was designed to help identify this point. For the reasons explained, though, the rigid application of that test has not been helpful in categorizing the new large projects designed to bring gas onshore from deep water production areas. For long lines designed to bring

gas onshore from deep water, we believe the place where gathering or collection ends and transportation begins is the point or points of potential connection with the existing interstate pipeline grid. Whether the lines actually interconnect there or not, we see little difference in function between an interstate transportation line that takes gas to shore and a newly built line that, for all practical purposes, runs parallel to it and serves the same purpose of moving gas to shore.

One of the principles underlying our policy on the OCS is to hold all owners of facilities that perform similar functions to the same regulatory requirements that our statutory jurisdiction allows. It would be inconsistent to allow new, large pipelines that perform a function no different from nearby existing lines subject to NGA regulation to operate outside the framework of Order No. 636 while, at the same time, applying the requirements of Order No. 636 to existing pipelines with the same physical features and function.

For example, in the *SGPC* order,<sup>26</sup> the Commission is issuing a certificate under NGA section 7(c) for that portion of the proposed facility that performs a transportation function. The Commission will regulate the WD 143 to Venice Line as an NGA facility because, under the Commission's "primary function" test, the line is "representative of the other long-haul transportation systems in the area that serve to move OCS production, that has been aggregated at interconnection platforms, to shore for processing and subsequent redelivery onto the onshore interstate transportation grid."<sup>27</sup> Like other interstate pipelines performing the same function, the Commission will require *SGPC* to comply with all the requirements of Order No. 636.<sup>28</sup>

The Commission will continue to exercise rate jurisdiction for gathering facilities that are owned by natural gas companies (irrespective of whether these natural gas companies are existing interstate pipelines or new deep water producers that also own transportation

<sup>26</sup> See Docket No. CP96-9-000, issued contemporaneously with this policy statement.

<sup>27</sup> *Id.*, slip op. at 20.

<sup>28</sup> In response to the interstate pipelines' concerns about competing on the OCS with unregulated entities, the Commission notes it recently issued a policy statement that allows a pipeline to negotiate creative approaches to pricing other than traditional cost-of-service ratemaking if its cost-based recourse rate is available. See *Alternatives to Traditional Cost-of-Service Ratemaking for Natural Gas Pipelines*, 74 FERC ¶ 61,076 (1996).

<sup>24</sup> Viosca Knoll Gathering System, 66 FERC ¶ 61,237 (1994), *reh'g denied*, 68 FERC ¶ 61,050 (1994).

<sup>25</sup> "In 1991, total costs for the average exploratory natural gas well in the lower 48 states were almost \$600,000 onshore, and over \$5 million offshore. In deep water, a tension leg platform in 3,000 feet of water can cost a billion dollars." U.S. Senate Committee on Energy and Natural Resources, Report 103-248 (April 11, 1994) (commenting on S. 318, a draft of what became the Outer Continental Shelf Deep Water Royalty Relief Act, Title III, P.L. 104-58, enacted November 28, 1995).

facilities).<sup>29</sup> As noted in the *SGPC* order, the Commission will have jurisdiction over rates charged by SGPC for gathering services over those facilities upstream of the WD 143 platform.

Moreover, in addition to our NGA "in connection with" jurisdiction over gathering rates charged by natural gas companies, the Commission has jurisdiction pursuant to sections 5(e) and 5(f) of the OCSLA. Such jurisdiction is not restricted to interstate pipelines subject to the Commission's NGA jurisdiction, but rather extends to all pipelines on the OCS, including gathering lines owned by non-interstate pipelines.<sup>30</sup> The Commission acknowledged this jurisdiction in Order Nos. 509 and 509-A. In Order No. 509-A, the Commission stated that "the open-access mandate of the OCSLA applies to all pipeline operations on the OCS, and will consider appropriate measures for remedying discriminatory access to other OCS facilities on a case by case basis."<sup>31</sup>

The Commission continues to believe this and will treat seriously, and respond promptly to, complaints filed pursuant to the OCSLA by shippers on OCS gathering pipelines that are not otherwise subject to the Commission's NGA "in connection with" jurisdiction. The Commission interprets the nondiscrimination mandates of sections 5(e) and 5(f) of the OCSLA to require, at a minimum, nondiscriminatory access and nondiscrimination with respect to rates and terms and conditions of service.

In particular, the Commission believes it has the authority under the OCSLA to take those steps necessary to guarantee that all OCS pipelines, including those not subject to the NGA, provide fair and unrestricted access in

a manner that ensures the efficient development of OCS natural gas resources. The Commission stated in Order No. 509 that if it received complaints it would "use its ancillary authority, its authority under sections 4 and 5 of the NGA, and its authority under section 5 of the OCSLA, as appropriate under the circumstances presented."<sup>32</sup>

In sum, the Commission will continue to determine the primary function of offshore facilities on a case-by-case basis, as the majority of commenters advocate. However, in applying our primary function test to facilities offshore, in recognition of the technology and topography particular to operations in deep water, we will presume facilities located in deep water are primarily engaged in gathering or production. Other than this clarification regarding the primary function of facilities offshore, after consideration of the comments, we find no cause to seek to alter our regulatory authority under the NGA and OCSLA over natural gas facilities and services on the OCS. By the Commission.

Lois D. Cashell,  
*Secretary.*

#### Appendix

##### *Parties submitting comments in Docket No. RM96-5-000:*

American Gas Association (AGA)  
Amoco Energy Trading Corporation  
jointly with Amoco Production Company (Amoco)  
ANR Pipeline Company (ANR)  
Atlanta Gas Light Company jointly with  
Chattanooga Gas Company (Atlanta)  
Brooklyn Union Gas Company  
(Brooklyn Union)  
Blue Dolphin Exploration Company  
(Blue Dolphin Exploration)  
Blue Dolphin Pipe Line Company (Blue  
Dolphin Pipe Line)  
Centana Gathering Company (Centana)  
Chemical Manufacturers Association  
(Chemical Manufacturers) \*  
Columbia Gas Transmission Corporation  
jointly with Columbia Gulf  
Transmission Company (Columbia)  
Consolidated Natural Gas Company  
(CNG)  
Energy Development Corporation  
(Energy Development)  
Enron Interstate Pipelines (Enron)  
Enserch Exploration, Inc. (Enserch)  
Independent Petroleum Association of  
America (IPAA)

Interstate Natural Gas Association of  
America (INGAA)  
Koch Gateway Pipeline Company  
(Koch)  
Leviathan Gas Pipeline Company  
(Leviathan)  
Marathon Oil Company  
Maryland Department of the  
Environment \*  
Minerals Management Service, U.S.  
Department of Interior (MMS) \*  
Natural Gas Pipeline Company of  
America (Natural)  
Natural Gas Supply Association  
(NGSA) \*  
OCS Producers  
PanEnergy Companies (PanEnergy)  
Process Gas Consumers Group jointly  
with American Iron and Steel  
Institute and Georgia Industrial Group  
(Process Gas Consumers)  
Sea Robin Pipeline Company (Sea  
Robin)  
State of Louisiana (Louisiana)  
Tejas Power Corporation (Tejas)  
Tennessee Gas Pipeline Company  
(Tennessee)  
Texaco Natural Gas Inc. (Texaco)  
Total Minatome Corporation (Total  
Minatome)  
Vastar Resources, Inc. (Vastar)  
Venice Gathering Company (Venice)  
Williams Field Services Group, Inc.  
jointly with Transcontinental Gas  
Pipe Line Corporation (Williams Field  
Services)

\* Filed out-of-time.

[FR Doc. 96-5066 Filed 3-4-96; 8:45 am]

BILLING CODE 6717-01-P

#### [Docket No. CP96-201-000, et al.]

##### **Algonquin Gas Transmission Company, et al.; Natural Gas Certificate Filings**

February 26, 1996.

Take notice that the following filings have been made with the Commission:

##### **1. Algonquin Gas Transmission Company**

[Docket No. CP96-201-000]

Take notice that on February 20, 1996, Algonquin Gas Transmission Company (Algonquin), 1284 Soldiers Field Road, Boston, Massachusetts 02135 filed an application pursuant to Sections 7(c) of the Natural Gas Act and Part 157 of the Commission's Regulations for a certificate of public convenience and necessity authorizing the construction and operation of certain facilities necessary to connect Algonquin's existing pipeline system with facilities owned by The Connecticut Light and Power Company (CL&P) in Middletown, Connecticut (the "Middletown Plant").

<sup>29</sup> Under sections 4 and 5 of the NGA, the Commission has jurisdiction over the rates and charges received by natural gas companies for or "in connection with" the jurisdictional transportation of gas. Thus, an interstate pipeline's gathering rates generally are subject to the Commission's jurisdiction because they are in connection with the pipeline's jurisdictional transportation services. See *Northern Natural Gas Company*, 929 F.2d 1261 (8th Cir. 1991), *cert. denied*, 112 S.Ct. 169 (1991).

<sup>30</sup> The only pipelines that may be exempt from the Commission's jurisdiction under the OCSLA are certain "feeder lines," which are defined in section 5(f) of the OCSLA, 43 USC 1334(f)(2), as a pipeline which feeds into a facility where oil and gas are "first collected" or a facility where oil and gas are "first separated, dehydrated, or otherwise processed." Moreover, these "feeder lines" only may be exempted from the requirements of the OCSLA by order of the Commission.

<sup>31</sup> Interpretation of, and Regulations Under, Section 5 of the Outer Continental Shelf Lands Act (OCSLA) Governing Transportation of Natural Gas by Interstate Natural Gas Pipelines on the Outer Continental Shelf, 54 FR 8,301 (February 28, 1989), FERC Stats. & Regs. ¶ 30,848 at 31,334 (1989).

<sup>32</sup> Interpretation of, and Regulations Under, Section 5 of the Outer Continental Shelf Lands Act (OCSLA) Governing Transportation of Natural Gas by Interstate Natural Gas Pipelines on the Outer Continental Shelf, 53 FR 50,925 (December 19, 1988), FERC Stats. & Regs. ¶ 30,842 at 31,289 (1988).

Algonquin's application is on file with the Commission and open to public inspection.

Algonquin proposes to construct and operate approximately 8.4 miles of 20-inch pipeline lateral, a meter station and appurtenant facilities (the "Middletown Lateral"), extending from a point on Algonquin's existing mainline system in Glastonbury, Connecticut, south through Portland, Connecticut and across the Connecticut River to CL&P's Middletown Plant. Algonquin plans to construct the lateral facilities generally within CL&P's electric transmission light right-of-way. Algonquin states that the facilities would be constructed during the Spring and Summer of 1997 for an in-service date of July 1, 1997; and, the cost of the facilities is estimated to be approximately \$15.1 million.

Algonquin proposes to construct and operate the Middletown Lateral for the transportation of up to 82,500 MMBtu per day of natural gas for CL&P. Algonquin states that CL&P intends to use the gas as an alternate fuel for the No. 2 and No. 3 Units of its electric generating station at the Middletown Plant. Algonquin and CL&P have executed a precedent agreement dated February 15, 1996, contemplating firm transportation service under Algonquin's Rate Schedule AFT-1 following the construction of the facilities necessary to provide that service. Algonquin states that upon satisfaction of the conditions specified in the precedent agreement, principally Commission approval, Algonquin and CL&P will execute a service agreement for transportation service for a term of twenty years.

*Comment date:* March 18, 1996, in accordance with Standard Paragraph F at the end of this notice.

## 2. Williston Basin Interstate Pipeline Company

[Docket No. CP96-202-000]

Take notice that, on February 20, 1996, Williston Basin Interstate Pipeline Company (Williston Basin), 200 North Third Street, Suite 300, Bismarck, North Dakota 58501, filed a request, pursuant to its blanket certificate in Docket No. CP82-487-000 *et al.* (30 FERC ¶ 61,143), section 7 of the Natural Gas Act (NGA) and §§ 157.205 and 157.211 of the Commission's Regulations, for authorization to construct and operate a new metering station and appurtenant facilities to provide deliveries of transportation service volumes to Montana-Dakota Utilities Company (Montana-Dakota), a local distribution company, for ultimate use by Dunbar Resorts of Deadwood, South Dakota, all

as more fully set forth in the request, which is on file with the Commission and open to public inspection.

Williston Basin states that the proposed facilities are estimated to cost \$17,000 and will consist of a meter, regulators, and miscellaneous gauges and valves. The delivery point that Williston Basin will use to serve Dunbar Resorts is an existing farm tap which was installed in the late 1950's to serve a right-of-way grantor. Williston Basin states that the Commission authorized this tap, and the service Williston Basin provides to Montana-Dakota through it, in Williston Basin's above-referenced blanket certificate proceeding. Williston Basin further states that the transportation service it will provide to Montana-Dakota through the proposed facilities will be performed under its FERC Gas Tariff, Second Revised Volume No. 1, under Rate Schedules FT-1 and/or IT-1.

The proposed meter station facilities are to be located on existing pipeline right-of-way, in the NE¼ of the NW¼ of Section 14, T5N, R3E, in Lawrence County, South Dakota. Williston Basin states that the currently estimated maximum quantity of natural gas to be delivered to Montana-Dakota through this meter station is 120 Mcfd, that the proposed facilities will be designed to deliver gas at a rate of up to 1,200 Mcfd, and that the costs incurred to increase the design capacity of the facilities in excess of current projected usage are minimal and will allow for expected future growth in the area.

Williston Basin adds that all of the proposed facilities will be enclosed within a security fence, that such enclosure will be approximately 10 feet by 15 feet, and that the soil within such area will be sterilized and covered with aggregate to prevent any undesirable vegetation growth.

*Comment date:* April 11, 1996, in accordance with Standard Paragraph G at the end of this notice.

## 3. Northern Natural Gas Company

[Docket No. CP96-203-000]

Take notice that on February 20, 1996, Northern Natural Gas Company (Northern), 1111 South 103rd Street, Omaha, Nebraska 68124-1000, filed in Docket No. CP96-203-000 a request pursuant Sections 157.205(b) and 157.212 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205(b) and 157.212) for a authority to upgrade an existing delivery point, located in Olmsted County, Minnesota, to accommodate natural gas deliveries to UtiliCorp United, Inc. (UCU) under Northern's blanket certificate issued in Docket No.

CP82-401-000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Northern states that service would be provided to UCU under currently effective interruptible throughput service agreement(s). Northern asserts that the upgrade of Elcor Asphalt TBS is required in order to provide additional transportation service to the Elcor Asphalt plant.

It is further asserted that the incremental volumes that would be delivered to UCU at the Elcor Asphalt TBS are 296 MMBtu on a peak day and 52,435 MMBtu on an annual basis. Northern states that the total estimated cost to upgrade the existing Elcor Asphalt TBS is \$9,500.

*Comment date:* April 11, 1996, in accordance with Standard Paragraph G at the end of this notice.

## 4. Columbia Gas Transmission Corporation

[Docket No. CP96-204-000]

Take notice that on February 20, 1996, Columbia Gas Transmission Corporation (Columbia), 1700 MacCorkle Avenue, S.E., Charleston, West Virginia 25314, filed in Docket No. CP96-204-000 a request pursuant to Sections 157.205 and 157.212 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.212) for authorization to construct and operate a new natural gas delivery point located in Goochland County, Virginia under Columbia's blanket certificate issued in Docket No. CP83-76-000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Columbia proposes to construct and operate a new delivery point (West Creek) consisting of a 4-inch tap, a filter separator, and a 4-inch meter for Commonwealth Gas Services, Inc. (COS). Columbia states that the new facilities would cost approximately \$102,000 and COS would reimburse Columbia for these costs.

Columbia states that COS would receive 500 Dth of gas per day and 400,000 Dth of gas per year at the West Creek point and would reduce by like quantity the amount of gas it receives at the existing Monocan delivery point. Columbia mentions that since COS has not requested an increase in its firm entitlement, there is no impact on Columbia's existing peak day obligations.

*Comment date:* April 11, 1996, in accordance with Standard Paragraph G at the end of this notice.



## 5. ANR Pipeline Company

[Docket No. CP96-208-000]

Take notice that on February 21, 1996, ANR Pipeline Company (ANR), 500 Renaissance Center, Detroit, Michigan 48243, filed in Docket No. CP96-208-000 an application pursuant to Section 7(c) of the Natural Gas Act for authorization to use additional work space associated with a pipeline replacement project in St. Landry Parish, Louisiana, all as more fully set forth in the application on file with the Commission and open to public inspection.

ANR proposes to replace a 1.2 mile segment of its Southeast Mainline because of increased population density and in order to satisfy U.S. Department of Transportation safety regulations. ANR states that in order to accomplish this replacement construction it will have to utilize work areas which may not have been included in the scope of the authorizations for these facilities when they were originally certificated and constructed. Therefore, ANR requests the temporary use of work space adjacent to the right-of-way of the pipeline being replaced. It is stated that the construction will be done under the authority of Section 2.55 of the Commission's Regulations, which authorizes replacement within the existing right-of-way.

*Comment date:* March 18, 1996, in accordance with Standard Paragraph F at the end of this notice.

## Standard Paragraphs

F. Any person desiring to be heard or make any protest with reference to said filing should on or before the comment date file with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice

and Procedure, a hearing will be held without further notice before the Commission or its designee on this filing if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for the applicant to appear or be represented at the hearing.

G. Any person or the Commission's staff may, within 45 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

*Secretary.*

[FR Doc. 96-5002 Filed 3-4-96; 8:45 am]

BILLING CODE 6717-01-P

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-5434-3]

### Agency Information Collection Activities Under OMB Review; New Source Performance Standards, Calciners and Dryers in the Mineral Processing Industry; OMB# 2060-0251, EPA# 0746.03

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (44 U.S.C. 3507(A)(1)(D)), this notice announces that the Information Collection Request (ICR) for Standards of Performance for New Stationary Sources—Calciners and Dryers in the Mineral Industry (Subpart UUU) described below has been forwarded to the Office of Management

and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected burden and cost; where appropriate, it includes the actual date collection instrument.

**DATES:** Comments must be submitted on or before April 4, 1996.

**FOR FURTHER INFORMATION OR A COPY CALL:** Sandy Farmer at EPA, (202) 260-2740, and refer to EPA ICR No. 746.03 and OMB No. 2060-0251.

**SUPPLEMENTARY INFORMATION:** *Title:* Standards of Performance for Calciners and Dryers in Mineral Industries (Subpart UUU) OMB Control No. 2060-0251; EPA ICR No. 0746.03. This is a request for revision of a currently approved collection.

*Abstract:* The Administrator has judged that PM emissions from calciners and dryers in the mineral industry cause or contribute to air pollution that may reasonably be anticipated to endanger public health or welfare. Owners/operators of calciners and dryers must notify EPA of construction, modification, startups, shut downs, date and results of initial performance test. Owners/operators with facilities using any wet scrubbing device shall install, calibrate, and maintain continuous monitoring devices to measure pressure drop and flow rate. Weekly records of the pressure drop and flow rate are to be maintained, and semi-annual reports are to be submitted when the pressure drop is less than 90% of the average value, and/or the flow rate is less than 80% or greater than 120%, from the most recent performance test recorded according to § 60.736(c).

In order to ensure compliance with the standards promulgated to protect public health, adequate reporting and recordkeeping is necessary. In the absence of such information enforcement personnel would be unable to determine whether the standards are being met on a continuous basis, as required by the Clean Air Act.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15. The Federal Register notice required under 5 CFR 1320.8(d), soliciting comments on this collection of information was published on September 29, 1995 and no comments were received.

*Burden Statement:* The annual public reporting and recordkeeping burden for this collection of information is estimated to average 51 hours per



response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

*Respondents/Affected Entities:* 155.  
*Estimated Number of Responses:* 310.  
*Frequency of Response:* 2.

*Estimated Total Annual Hour Burden:* 15,668 hours.

*Estimated Total Annualized Cost Burden:* \$477,090.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the following addresses. Please refer to EPA ICR No. 0746.03 and OMB Control No. 2060-0251 in any correspondence.

Ms. Sandy Farmer, U.S. Environmental Protection Agency, OPPE Regulatory Information Division (2136), 401 M Street, SW., Washington, DC 20460 and

Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

Dated: February 27, 1996.

Joseph Retzer,  
*Director, Regulatory Information Division.*  
[FR Doc. 96-5030 Filed 3-4-96; 8:45 am]

BILLING CODE 6560-50-M

[FRL-5434-4]

#### **TSCA; Agency Information Collection Activities Under OMB Review**

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the Office of Prevention, Pesticides and Toxic Substances (OPPTS) is seeking the renewal of an existing Information

Collection Request (ICR) from the Office of Management and Budget (OMB). OPPTS has forwarded the following ICR to OMB: TSCA Section 12(b) Notification of Chemical Exports (OMB Control No. 2070-0030, EPA ICR No. 795), which is abstracted below. The ICR describes the nature of the information collection and its expected cost and burden; where appropriate, it includes the actual data collection instrument. EPA requested comments on this ICR and its proposed renewal in a Federal Register notice on September 29, 1995 (60 FR 50568). The sole comment received was considered prior to finalizing this ICR.

**DATES:** Comments must be submitted on or before April 4, 1996.

**FOR FURTHER INFORMATION OR A COPY CALL:** Sandy Farmer at EPA (202) 260-2740, and refer to EPA ICR No. 0795.09.

**SUPPLEMENTARY INFORMATION: Title:** Notification of Chemical Exports (OMB Control No. 2070-0030, EPA ICR No. 0795). This is a request for extension of a currently approved information collection which expires on April 30, 1996.

**Abstract:** Section 12(b)(2) of the Toxic Substances Control Act (TSCA) requires that any person who exports or intends to export to a foreign country a chemical substance or mixture that is regulated under TSCA sections 4, 5, 6 and/or 7 submit to EPA notification of such export or intent to export. Upon receipt of notification, EPA will advise the government of the importing country of the U.S. regulatory action with respect to that substance. EPA uses the information obtained from the submitter via this collection to advise the government of the importing country. Responses to the collection of information are mandatory (see 40 CFR part 707). Respondents may claim all or part of a notice confidential. EPA will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures in TSCA section 14 and 40 CFR part 2. However, notwithstanding any claims of confidentiality, the government of the importing country will be notified of the export of the substances in question.

**Burden Statement:** The annual public reporting and recordkeeping burden for this collection of information is estimated to average 0.55 hours per response. This estimate includes the time needed to review instructions; develop, acquire, install and utilize technology and systems for the purposes of collecting, validating and verifying information, processing and maintaining information, and disclosing

and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. No person is required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are displayed in 40 CFR Part 9.

**Respondents/Affected Entities:** Those which export or engage in wholesale sales of chemicals.

**Estimated No. Of Respondents:** 200.

**Estimated Total Annual Burden on Respondents:** 3,800 hours.

**Frequency of Collection:** On occasion.

Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to the following address. Please refer to EPA ICR No. 0795.09 and OMB Control No. 2070-0030 in any correspondence.

Ms. Sandy Farmer, U.S. Environmental Protection Agency, Information Policy Branch (2136), 401 M Street, SW., Washington, DC 20460

and  
Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

Dated: February 27, 1996.

Joseph Retzer,  
*Director, Regulatory Information Division.*  
[FR Doc. 96-5031 Filed 3-4-96; 8:45 am]

BILLING CODE 6560-50-M

[OPPTS-62152; FRL-4985-9]

#### **Asbestos-Containing Materials in Schools; State Request for Waiver from Requirements**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of proposed waiver.

**SUMMARY:** EPA has received from the State of Maine a request for a waiver from the requirements of 40 CFR part 763, Subpart E, Asbestos-Containing Materials in Schools. This document announces an opportunity for public review and comment on the State waiver request.

**DATES:** Comments on the waiver request must be received by May 6, 1996.

**ADDRESSES:** Written comments must be sent in triplicate, identified by the

docket control number OPPTS-62152 to: James M. Bryson, Regional Abatement Coordinator, Environmental Protection Agency, OEP 309 Region I, John F. Kennedy Federal Building, Boston, MA 02203-0001. Copies of the Maine waiver request are on file and may be reviewed at the EPA Region I Office.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: bryson.jamesm@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number OPPTS-62152. No CBI should be submitted through e-mail. Electronic comments on this document may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in the SUPPLEMENTARY INFORMATION unit of this document. **FOR FURTHER INFORMATION CONTACT:** James M. Bryson at the address listed above.

**SUPPLEMENTARY INFORMATION:** This document is issued under the authority of Title II of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2641, *et seq.* TSCA Title II was enacted as part of the Asbestos Hazard Emergency Response Act (AHERA), Pub. L. 99-519. AHERA is the name commonly used to refer to the statutory authority for EPA's rules affecting asbestos in schools. For purposes of this document, EPA will use the AHERA designation. In the Federal Register of October 30, 1987 (52 FR 41846), EPA issued a final rule as required in AHERA, the Asbestos-Containing Materials in Schools Rule (40 CFR part 763, Subpart E), which requires all Local Education Agencies (LEAs) to identify Asbestos-Containing Building Materials (ACBMs) in their school buildings and to take appropriate actions to control the release of asbestos fibers. The LEAs are required to describe their asbestos control activities in management plans, which must be available to all concerned persons and submitted to the State Governor's Designee. The rule requires LEAs to use specially trained and accredited persons to conduct inspections for asbestos, develop management plans, and design and conduct actions to control asbestos.

The recordkeeping and reporting burden associated with waiver requests was cleared under OMB control number 2070-0091. This document merely

announces the Agency's receipt of a waiver request and therefore impose no additional burden beyond that which was covered under existing OMB control number 2070-0091. Send any comments regarding the burden estimate or any other aspect of this collection to Chief, Information Policy Branch (2136), U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460 and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, Attention: Desk Officer.

Under section 203 of TSCA Title II, EPA may, upon request of a State Governor and after notice and comment and opportunity for a public hearing in the State, waive in whole or in part the requirements of the rule promulgated under section 203, if the State has established and is implementing or intends to implement a program of asbestos inspection and management which is at least as stringent as the requirements of 40 CFR part 763, Subpart E. The AHERA rule requests specific information be included in a waiver request submitted to EPA, establishes a process for reviewing waiver requests, and sets forth procedures for oversight and rescission of waivers granted to the States.

The rule requires States seeking waivers to submit requests to the Regional Administrator for the EPA Region in which the State is located. EPA is hereby issuing a notice in the Federal Register announcing receipt of the request and soliciting written comments from the public pertaining to the State of Maine's asbestos waiver request, and Senate Bill 38 MSRA impact on the implementation and enforcement of Maine's Regulation 16B. Comments must be submitted by May 6, 1996. If during the comment period, EPA receives a written objection to the State's request, EPA will schedule a hearing to be held in the affected State after the close of the comment period.

On December 20, 1994, Assistant Attorney General Jon H. Edwards submitted to John P. DeVillars, Regional Administrator, EPA Region I, a request for a waiver under the AHERA 40 CFR 763.98. The request was received by the Regional Office on January 3, 1995. The State's submittal requested a waiver from all requirements of 40 CFR part 763, Subpart E.

The State's waiver request was complete in that it contained all of the following provisions which are required by the AHERA:

1. A copy of the State provisions and proposed provisions relating to its program of asbestos inspection and

management in schools for which the request is made.

2. The name of the State agency that is responsible for administering and enforcing the requirements for which a waiver is requested, the names and job titles of responsible officials in that agency, and phone numbers where the officials can be contacted.

3. Detailed reasons, supporting papers, and the rationale for concluding that the State's asbestos inspection and management program provisions for which the request is made are at least as stringent as the requirements of 40 CFR part 763, Subpart E.

4. A discussion of any special situations, problems, and needs pertaining to the waiver request accompanied by an explanation of how the State intends to handle them.

5. A statement of the resources that the State intends to devote to the administration and enforcement of the provisions relating to the waiver request.

6. Copies of any specific or enabling State laws and regulations relating to the request, including provisions for assessing criminal and/or civil penalties.

7. Assurance from the Governor/Attorney General or the lead agency that the lead agency has the legal authority necessary to carry out the requirements relating to the request.

EPA may waive some or all of the requirements of 40 CFR part 763, Subpart E if:

1. *The State has the legal authority necessary to carry out the provisions of asbestos inspection and management in schools relating to the waiver request.* The Maine Department of Environmental Protection recognizes that asbestos exposure in schools (and elsewhere) is a serious concern. The Maine General Assembly also recognized this, and during a 1987 legislative session a bill was passed authorizing the Air Pollution Control Division, Maine Department of Environmental Protection to implement State requirements under the AHERA, establish a certification program for abatement contractors, develop and implement asbestos work practices and exposure standard, collect fees, and levy fines. Effective June 30, 1993, Maine's revised asbestos regulation required the certification of all persons engaging in asbestos-related work. The requirement applies to all public and commercial buildings as well as schools. The revised regulation also contains more stringent work practices for asbestos abatement and expands the enforcement capabilities of the State in regards to false training documents submitted to

obtain certification. The Maine General Assembly has enacted authority for the Maine Air Quality Control Commission to enforce rules and regulations to minimize the risk to the public from the exposure to asbestos, including specifically, requirements for asbestos management plans to be submitted and implemented by schools. All requisite legislative/legal authority to implement the AHERA waiver program have been adopted, and no problems are anticipated in meeting waiver objectives.

2. *The State's asbestos inspection and management will be at least as stringent as the requirements of 40 CFR part, 763 Subpart E.* The requirements of Subpart E of 40 CFR part 763 have been adopted in its entirety, with the exception of §§ 763.97 and 763.98 into the Maine Air Quality Control Commission's Regulation No. 16B, Chapter 12A, "Emission Standards for Asbestos" School Requirements. The State intends to administer these regulations in a manner that would be at least as stringent as the requirements of 40 CFR part 763, Subpart E.

3. *The State has the appropriate enforcement resources to devote to the administration and enforcement of the provisions relating to the waiver request.* The State conducts routine AHERA inspections, abatement inspections and "for cause" inspections. Routine AHERA inspections result in a determination of compliance with the need to have and implement an adequate, updated management plan. Routine inspections focus on assessing compliance with the AHERA and State asbestos requirements, including such things as implementation of appropriate work practices, compliance with accreditation (State Certification) requirements and proper recordkeeping. "For cause" inspections, are initiated as a result of tips or complaints, and are made to assess compliance with any applicable State or EPA asbestos rules. The State will continue to update its existing Neutral Administrative Inspection Scheme (NAIS) in support of targeting LEAs and other "persons" for AHERA compliance inspections. The NAIS will include a specific method or criteria for selecting inspection targets and will comply with EPA's National Compliance Monitoring Strategies for AHERA. The State has devoted four full-time employees to the existing TSCA Enforcement Grant and will continue to devote at least that amount of time to stringently enforce the requirements of 40 CFR part 763, Subpart E. The State has completed an enforcement response policy to determine the most appropriate enforcement action for each

violation of the State's laws and regulations.

4. *The State has or will have qualified personnel to carry out the provisions relating to the waiver request.* The program will be carried out by staff in the Maine Department of Environmental Protection, Air Pollution Control Division. The State is currently well staffed on the TSCA Asbestos program. The staff is fully trained and certified as Building Inspector/Management Planners and Contractor/Supervisors. Two of three staff persons are conducting full AHERA inspections. One staff person is conducting Worker Protection inspections and is currently training to conduct full AHERA inspections. The fourth person administers the grant and works on case development resulting from inspections.

5. *The State will devote adequate resources to the administration and enforcement of the asbestos inspection and management provisions relating to the waiver request.* Based upon review by the EPA Region I Office, the Agency feels that the Maine Department of Environmental Protection has resources to effectively implement and administer the asbestos program in Maine.

6. *When specified by EPA, the State gives satisfactory assurances that necessary steps, including specific actions it proposes to take and a time schedule for their accomplishment, will be taken within a reasonable time to conform with applicable criteria in items 2 through 5 above.* Final approval of the program by EPA will require effective implementation and continued use of the EPA-approved NAIS, logging and tracking system, enforcement strategy/standard operating procedure, enforcement response policy, and communication strategy. EPA's final approval of the State's program will require the State to provide adequate resources to support the administration of the program.

The reporting and recordkeeping provisions relating to State waivers from the requirements of the Asbestos-Containing Materials in Schools Rule (40 CFR part 763) have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act and have been assigned OMB control number 2070-0091.

On June 16, 1993, Maine Governor Angus S. King signed Senate Bill 38 M.R.S.A. (S.B. 38). S.B. 38 M.R.S.A. may have an impact on enforcement of Maine's asbestos rules and regulations. S.B. 38 M.R.S.A. S.B. 38 appears to create a statutory privilege for environmental audits and a presumption against imposition of penalties for voluntary disclosures

arising out of an environmental self-evaluation. EPA is concerned that S.B. 38 restricts the enforcement options available to the State and, therefore, may not be as stringent as the AHERA. Prior to making a final decision on Maine's request for an AHERA waiver, the State, should clarify S.B. 38's impact on the State's enforcement capabilities. EPA intends to request a legal analysis from the State on whether S.B. 38 applies to Maine's asbestos rules and regulations, and if so, to what extent. In addition, EPA specifically requests public comment on this issue.

EPA with this document is hereby announcing receipt of the State's request and soliciting written comments from the public pertaining to the State of Maine's asbestos waiver request, and Senate Bill 38 M.R.S.A. impact on the implementation and enforcement of Maine's Regulation 8. Comments must be submitted by May 6, 1996. If during the comment period, EPA receives a written objection to the State's request, EPA will schedule a hearing to be held in the affected State after the close of the comment period.

A record has been established for this document under docket number "OPPTS-62152 including comments and data submitted electronically as described below. A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as confidential business information (CBI), is available for inspection from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is maintained in Region I at the location listed under the ADDRESSES unit of this document.

Electronic comments can be sent directly to EPA at:

bryson.jamesm@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this document, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

## Lists of Subjects

Environmental protection and  
Asbestos.

Dated: February 14, 1996.

John P. DeVillars,

*Regional Administrator, Region I.*

[FR Doc. 96-4968 Filed 3-4-96; 8:45 am]

BILLING CODE 6560-50-F

## EXECUTIVE OFFICE OF THE PRESIDENT

### Office of National Drug Control Policy

**AGENCY:** Executive Office of the President, Office of National Drug Control Policy.

**ACTION:** The Drug Control Research, Data, and Evaluation Committee (DCRDEC); Notice of establishment.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, the Director of the Office of National Drug Control Policy has established the Drug Control Research, Data, and Evaluation Committee (DCRDEC).

The Committee shall provide an avenue of communications by which a distinguished expert group representing scientific, engineering, law enforcement, treatment, and associated international scientific communities may advise the Director of the Office of National Drug Control Policy (ONDCP) on questions related to national drug control research. In pursuing this objective, the DCRDEC may operate in subgroups composed of selected committee members to conduct detailed examinations of specific issues related to national drug control policy research.

The Committee will identify gaps in current data collection to improve the generation of accurate and useful information on which to base national drug control policy. It will function solely as an advisory body and in compliance with the provisions of the Federal Advisory Committee Act. Its charter will be filed under the Act fifteen (15) days from the date of this publication.

The Committee will be comprised of approximately fourteen members. The full DCRDEC subgroup will meet approximately twice per year in plenary sessions at the convenience of the Director of the ONDCP. In addition, various sub-committees meet periodically throughout the year.

**FOR FURTHER INFORMATION CONTACT:** Comments and questions regarding the Drug Control Research, Data, and Evaluation Committee (DCRDEC) should be directed to Mr. Edward H. Jurith, General Counsel, Office of National

Drug Control Policy, Executive Office of the President, 750 17th Street, N.W., Washington, D.C. 20500, (202) 395-6709.

Signed at Washington, DC, this 26th day of February, 1996.

Edward H. Jurith,  
*General Counsel.*

[FR Doc. 96-5021 Filed 3-4-96; 8:45 am]

BILLING CODE 3180-02-P

## FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA-1104-DR]

### Alabama; Major Disaster and Related Determinations

**AGENCY:** Federal Emergency Management Agency (FEMA).

**ACTION:** Notice.

**SUMMARY:** This is a notice of the Presidential declaration of a major disaster for the State of Alabama (FEMA-1104-DR), dated February 23, 1996, and related determinations.

**EFFECTIVE DATE:** February 23, 1996.

**FOR FURTHER INFORMATION CONTACT:** Pauline C. Campbell, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-3606.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that, in a letter dated February 23, 1996, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*), as follows:.

I have determined that the damage in certain areas of the State of Alabama, resulting from a severe winter storm, ice and flooding on February 1-12, 1996, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act ("the Stafford Act"). I, therefore, declare that such a major disaster exists in the State of Alabama.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas. Hazard Mitigation Assistance may be provided at a later date, if warranted. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance or Hazard Mitigation will be limited to 75 percent of the total eligible costs.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for

Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint Glenn C. Woodard of the Federal Emergency Agency to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the State of Alabama to have been affected adversely by this declared major disaster:

Cullman, DeKalb, Jackson, Limestone, Marshall and Morgan for Public Assistance. (Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

James L. Witt,

*Director.*

[FR Doc. 96-5092 Filed 3-4-96; 8:45 am]

BILLING CODE 6718-02-P

[FEMA-1102-DR]

### Idaho; Amendment to Notice of a Major Disaster Declaration

**AGENCY:** Federal Emergency Management Agency (FEMA).

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster for the State of Idaho (FEMA-1102-DR), dated February 11, 1996, and related determinations.

**EFFECTIVE DATE:** February 27, 1996.

**FOR FURTHER INFORMATION CONTACT:** Pauline C. Campbell, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-3606.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that the incident period for this disaster is closed effective February 23, 1996.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

G. Clay Hollister,

*Deputy Associate Director, Response and Recovery Directorate.*

[FR Doc. 96-5090 Filed 3-4-96; 8:45 am]

BILLING CODE 6718-02-P

[FEMA-1105-DR]

### Montana; Major Disaster and Related Determinations

**AGENCY:** Federal Emergency Management Agency (FEMA).

**ACTION:** Notice.

**SUMMARY:** This is a notice of the Presidential declaration of a major

disaster for the State of Montana (FEMA-1105-DR), dated February 23, 1996, and related determinations.

**EFFECTIVE DATE:** February 23, 1996.

**FOR FURTHER INFORMATION CONTACT:** Pauline C. Campbell, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-3606.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that, in a letter dated February 23, 1996, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*), as follows:

I have determined that the damage in certain areas of the State of Montana, resulting from severe storms, flooding and ice jams on February 4, 1996 and continuing, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act ("the Stafford Act"). I, therefore, declare that such a major disaster exists in the State of Montana.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance and Hazard Mitigation in the designated areas. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance or Hazard Mitigation will be limited to 75 percent of the total eligible costs.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint David P. Grier, IV, of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the State of Montana to have been affected adversely by this declared major disaster:

Chouteau, Deer Lodge, Gallatin, Lewis and Clark, Lincoln, Meagher, Missoula, Ravalli, Sanders and Silver Bow for Public Assistance and Hazard Mitigation Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

James L. Witt,

*Director.*

[FR Doc. 96-5093 Filed 3-4-96; 8:45 am]

BILLING CODE 6718-02-P

#### [FEMA-1103-DR]

#### North Carolina; Major Disaster and Related Determinations

**AGENCY:** Federal Emergency Management Agency (FEMA).

**ACTION:** Notice.

**SUMMARY:** This is a notice of the Presidential declaration of a major disaster for the State of North Carolina (FEMA-1103-DR), dated February 23, 1996, and related determinations.

**EFFECTIVE DATE:** February 23, 1996.

**FOR FURTHER INFORMATION CONTACT:** Pauline C. Campbell, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-3606.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that, in a letter dated February 23, 1996, the President declared a major disaster under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*), as follows:

I have determined that the damage in certain areas of the State of North Carolina, resulting from a winter storm on February 2-9, 1996, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act ("the Stafford Act"). I, therefore, declare that such a major disaster exists in the State of North Carolina.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas. Hazard Mitigation Assistance may be provided at a later date, if warranted. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance or Hazard Mitigation will be limited to 75 percent of the total eligible costs.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby appoint Glenn C. Woodard of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the State of North Carolina to have been affected adversely by this declared major disaster:

Alexander, Burke, Caldwell, Catawba, Cherokee, Cleveland, Davidson, Forsyth, Gaston, Guilford, Halifax, Henderson, Iredell, Lincoln, McDowell, Polk, Stokes, Wilkes, and Yadkin for Public Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

James L. Witt,

*Director.*

[FR Doc. 96-5091 Filed 3-4-96; 8:45 am]

BILLING CODE 6718-02-P

#### [FEMA-1099-DR]

#### Oregon; Amendment to Notice of a Major Disaster Declaration

**AGENCY:** Federal Emergency Management Agency (FEMA).

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster for the State of Oregon (FEMA-1099-DR), dated February 9, 1996, and related determinations.

**EFFECTIVE DATE:** February 23, 1996.

**FOR FURTHER INFORMATION CONTACT:** Pauline C. Campbell, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-3606.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that the incident period for this disaster is closed effective February 21, 1996.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance)

William C. Tidball,

*Associate Director, Response and Recovery Directorate.*

[FR Doc. 96-5094 Filed 3-4-96; 8:45 am]

BILLING CODE 6718-02-P

#### [FEMA-1099-DR]

#### Oregon; Amendment to Notice of a Major Disaster Declaration

**AGENCY:** Federal Emergency Management Agency (FEMA).

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster for the State of Oregon, (FEMA-1099-DR), dated February 9, 1996, and related determinations.

**EFFECTIVE DATE:** February 26, 1996.

**FOR FURTHER INFORMATION CONTACT:** Pauline C. Campbell, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-3606.

**SUPPLEMENTARY INFORMATION:** The notice of a major disaster for the State of Oregon, is hereby amended to include

the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of February 9, 1996:

Coos, and Deschutes Counties for Individual Assistance.

Gilliam, and Morrow Counties for Individual Assistance (already designated for Public Assistance and Hazard Mitigation).

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance)

G. Clay Hollister,

*Deputy Associate Director, Response and Recovery Directorate.*

[FR Doc. 96-5095 Filed 3-4-96; 8:45 am]

BILLING CODE 6718-02-P

#### [FEMA-1093-DR]

#### **Pennsylvania; Amendment to Notice of a Major Disaster Declaration**

**AGENCY:** Federal Emergency Management Agency (FEMA).

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster for the Commonwealth of Pennsylvania, (FEMA-1093-DR), dated January 21, 1996, and related determinations.

**EFFECTIVE DATE:** February 27, 1996.

**FOR FURTHER INFORMATION CONTACT:** Pauline C. Campbell, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-3606.

**SUPPLEMENTARY INFORMATION:** The notice of a major disaster for the Commonwealth of Pennsylvania, is hereby amended to include the following area among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of January 21, 1996:

Forest County for Public Assistance (already designated for Individual Assistance and Hazard Mitigation).

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

G. Clay Hollister,

*Deputy Associate Director, Response and Recovery Directorate.*

[FR Doc. 96-5096 Filed 3-4-96; 8:45 am]

BILLING CODE 6718-02-P

#### [FEMA-3117-EM]

#### **Texas; Amendment to Notice of a Emergency Declaration**

**AGENCY:** Federal Emergency Management Agency (FEMA).

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of an emergency for the State of Texas, (FEMA-3117-EM), dated February 23, 1996, and related determinations.

**EFFECTIVE DATE:** February 27, 1996.

**FOR FURTHER INFORMATION CONTACT:** Pauline C. Campbell, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-3606.

**SUPPLEMENTARY INFORMATION:** The notice of an emergency for the State of Texas, is hereby amended to include the following area among those areas determined to have been adversely affected by the catastrophe declared an emergency by the President in his declaration of February 23, 1996:

Parker County for emergency assistance as defined in the declaration letter of February 23, 1996.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

G. Clay Hollister,

*Deputy Associate Director, Response and Recovery Directorate.*

[FR Doc. 96-5097 Filed 3-4-96; 8:45 am]

BILLING CODE 6718-02-P

#### [FEMA-1100-DR]

#### **Washington; Amendment to Notice of a Major Disaster Declaration**

**AGENCY:** Federal Emergency Management Agency (FEMA).

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster for the State of Washington (FEMA-1100-DR), dated February 9, 1996, and related determinations.

**EFFECTIVE DATE:** February 26, 1996.

**FOR FURTHER INFORMATION CONTACT:** Pauline C. Campbell, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-3606.

**SUPPLEMENTARY INFORMATION:** The notice of a major disaster for the State of Washington is hereby amended to include the following area among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of February 9, 1996:

Skagit County for Individual Assistance, Public Assistance, and Hazard Mitigation

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance)

G. Clay Hollister,

*Deputy Associate Director, Response and Recovery Directorate.*

[FR Doc. 96-5089 Filed 3-4-96; 8:45 am]

BILLING CODE 6718-02-P

## **FEDERAL MARITIME COMMISSION**

### **Notice of Agreement(s) Filed**

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 800 North Capitol Street, NW., 9th Floor. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the Federal Register in which this notice appears. The requirements for comments are found in section 572.603 of Title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

*Agreement No.:* 218-011530.

*Title:* Samson/Sea-Land Cooperative Working Agreement.

*Parties:* Samson Tug & Barge Sea-Land Service, Inc.

*Synopsis:* The proposed Agreement authorizes the parties to engage in an exclusive transshipment arrangement in the trade between Cordova, King Cove, and Sand Point, Alaska and points served via such ports and ports and points in Europe and Asia.

*Agreement No.:* 203-011531.

*Title:* Wilhelmsen/AADL/Safbank/Lykes Space Charter and Sailing Agreement.

*Parties:* American-Africa-Delmas Line (AADL), Lykes Bros. Steamship Co., Inc., Safbank Line Limited, Wilhelmsen Lines A/S.

*Synopsis:* The proposed Agreement authorizes the parties to parties to consult and agree upon the deployment of vessels, to charter or exchange space with one another, and rationalize sailings. The parties may also, on a voluntary and non-binding basis, consult and agree upon terms and conditions, rates, rate policy, charges, service items, terms and conditions of service contracts or tariffs maintained by any party or by any conference, rate or discussion agreement in trade from U.S. Atlantic and Gulf Coast ports and points and ports and points in West Africa.

*Agreement No.:* 224-200974.

*Title:* Tampa Port Authority/Tampa Bay International Terminals, Inc. Wharfage Incentive Agreement.

*Parties:* Tampa Port Authority ("Port"), Tampa Bay International Terminals, Inc. ("TBIT").

**Synopsis:** The proposed Agreement permits the Port to assess an incentive wharfage rate of \$1.05 per net ton to TBIT on movements of iron or steel wire in coils, subject to a minimum annual volume of 10,000 net tons.

Dated: February 29, 1996.

By Order of the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 96-5121 Filed 3-4-96; 8:45 am]

BILLING CODE 6730-01-M

### **Ocean Freight Forwarder License; Applicants**

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission applications for licenses as ocean freight forwarders pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718 and 46 CFR 510).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to contact the Office of Freight Forwarders, Federal Maritime Commission, Washington, DC 20573.

Desert Net, Inc., World Trade Center, 401 E. Pratt Street, Baltimore, MD 21202. Officers: Mohammad D. Al-Dhoheyan, Director; Mohammad D. Al-Ahmed, President

JF Hillebrand USA West Coast, Inc., 621 West Spain Street, Sonoma, CA 95476. Officers: Christophe Bernard, President; Dorothee Maier, Vice President

All America Freight Services Corp., 10913 NW. 30th Street, Suite 100, Miami, Florida 33172. Officers: Osvaldo Perez, President; Helen M. Layton, Vice President.

Dated: February 28, 1996.

Joseph C. Polking,

Secretary.

[FR Doc. 96-4985 Filed 3-4-96; 8:45 am]

BILLING CODE 6730-01-M

### **Ocean Freight Forwarder License Applicants**

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission applications for licenses as ocean freight forwarders pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718 and 46 CFR 510).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to contact the Office of Freight Forwarders, Federal Maritime Commission, Washington, DC 20573.

International Logistics, Inc., 11015 I Street, Omaha, NE 68137. Officers: Michael Contreras, President; Steve Pitzl, Vice President

American Worldwide, Inc., 5861 So. Kyrene Road, Suite #9, Tempe, AZ 85283. Officers: Nicholas J. Matyas, President; Nicholas W. Matyas, Corporate Secretary.

Dated: February 29, 1996.

[FR Doc. 96-5120 Filed 3-4-96; 8:45 am]

BILLING CODE 6730-01-M

### **FEDERAL RESERVE SYSTEM**

#### **Formations of, Acquisitions by, and Mergers of Bank Holding Companies**

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. § 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations, to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. § 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act, including whether the acquisition of the nonbanking company can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices" (12 U.S.C. § 1843). Any request for a hearing must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal. Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications

must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than March 29, 1996.

A. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. *Acadiana Bancshares, Inc.*, Lafayette, Louisiana; to become a bank holding company by acquiring 100 percent of the voting shares of LBA Savings Bank, Lafayette, Louisiana.

2. *Monticello Bancshares, Inc.*, Monticello, Georgia; to become a bank holding company by acquiring 100 percent of the voting shares of Bank of Monticello, Monticello, Georgia.

B. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Capitol Bancorp Ltd.*, Lansing, Michigan; to acquire 51 percent of the voting shares of Bank of Tucson, Tucson, Arizona (in organization).

2. *Home Financial Bancorp.*, Spencer, Indiana; to become a bank holding company by acquiring 100 percent of the voting shares of Owen Community Bank, s.b., Spencer, Indiana.

3. *LeMars Bancorporation, Inc.*, LeMars, Iowa; to merge with Brunsville Bancorporation, Inc., Brunsville, Iowa, and thereby indirectly acquire First State Bank, Brunsville, Iowa, and to merge with Merrill Bancorporation, Inc., Merrill, Iowa; and thereby indirectly acquire Farmers State Bank, Merrill, Iowa.

C. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. *Norwest Corporation*, Minneapolis, Minnesota; to acquire 100 percent of the voting shares of Union Texas Bancorporation, Inc., Laredo, Texas, and thereby indirectly acquire Union National Bank, Laredo, Texas.

D. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *R. Banking Limited Partnership*, Oklahoma City, Oklahoma; to acquire up to 49.99 percent of the voting shares of BancFirst Corporation, Oklahoma City, Oklahoma, and thereby indirectly acquire BancFirst, Oklahoma City, Oklahoma.

Board of Governors of the Federal Reserve System, February 28.

William W. Wiles,  
Secretary of the Board.

[FR Doc. 96-5004 Filed 3-4-96; 8:45 am]

BILLING CODE 6210-01-F



**Notice of Proposals to Engage in Permissible Nonbanking Activities or the Acquisition of Companies that are Engaged in Permissible Nonbanking Activities**

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. § 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to commence or to engage *de novo*, or to acquire or control voting securities or assets of a company that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.25 of Regulation Y (12 CFR 225.25) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for immediate inspection at the Federal Reserve Bank indicated. Once the notice has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act, including whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices" (12 U.S.C. § 1843). Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than March 19, 1996.

A. Federal Reserve Bank of Richmond (Lloyd W. Bostian, Jr., Senior Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. *NationsBank Corporation*, Charlotte, North Carolina; to acquire LDI Corporation, Cleveland, Ohio, and thereby engage in leasing technology and data processing equipment, telecommunications products, and other capital equipment and to engage in

commercial finance activities, pursuant to §§ 225.25(b)(5) and (b)(1)(iv) of the Board's Regulation Y.

B. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. *Community Trust Financial Services Corporation*, Hiram, Georgia; to acquire Community Loan Company, Hiram, Georgia, through its subsidiary, Personal Finance Service, Inc., Rossville, Georgia, and Rock City Enterprises, Inc., Rockmart, Georgia, and thereby engage in consumer finance business, credit insurance, and tax planning and preparation services, pursuant to §§ 225.25(b)(1)(i), 225.25(b)(8)(ii) and 225.25(b)(21) of the Board's Regulation Y. The activities will be conducted throughout the State of Georgia.

C. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Midstates Bancshares, Inc.*, Harlan, Iowa; to engage *de novo* through its subsidiary, Midstates Financial Services, Inc., Harlan, Iowa, in acting as principal, agent, or broker for credit related insurance, pursuant to § 225.25(b)(8)(i) of the Board's Regulation Y; and in any insurance agency activity in a place where the bank holding company or a subsidiary of the bank holding company has a lending office and that has a population not exceeding 5,000, pursuant to § 225.25(b)(8)(iii) of the Board's Regulation Y.

In addition, Applicant also proposes to engage *de novo* through its subsidiary, Midstates Trust and Farm Management, Inc., Harlan, Iowa, in trust functions and activities, including activities of a fiduciary, agency or custodial nature, pursuant to § 225.25(b)(3) of the Board's Regulation Y; and in real estate and personal property appraising, pursuant to § 225.25(b)(13) of the Board's Regulation Y.

D. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Texhoma Bancshares, Inc.*, Texhoma, Oklahoma; to acquire 100 percent of the nonvoting, nonconvertible preferred shares of Texhoma Homes, Inc., Texhoma, Oklahoma, and thereby engage in the development of low-to-moderate residential housing, pursuant to § 225.25(b)(6) of the Board's Regulation Y.

Comments regarding this application must be received by March 11, 1996.

Board of Governors of the Federal Reserve System, February 28, 1996.

William W. Wiles,

*Secretary of the Board.*

[FR Doc. 96-5005 Filed 3-4-96; 8:45 am]

BILLING CODE 6210-01-F

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[INFO-96-10]

**Proposed Data Collections Submitted for Public Comment and Recommendations**

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639-3453.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Wilma Johnson, CDC Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

**Proposed Projects**

1. **Supplement to HIV/AIDS Surveillance (SHAS)—Extension—(0920-0262)** There continues to be significant interest from public health, community, minority groups, and affected groups in obtaining more information on persons with HIV/AIDS infection. Since 1989, the Centers for Disease Control and Prevention (CDC), in collaboration with 12 state and local health agencies, has collected data through the national Supplemental HIV/AIDS Surveillance (SHAS) project. The objective of this project is to obtain increased descriptive information on



persons with newly reported HIV and AIDS infections, including socioeconomic characteristics, risk behaviors, use of health care services, women's reproductive history and children's health, and information on

disabilities. This information supplements information that is routinely collected through national HIV/AIDS surveillance. The information gained from SHAS is used to improve our understanding of minority issues

related to the epidemic of HIV, target educational efforts to prevent transmission, and improve services for persons with HIV disease.

Respondents	No. of respondents	No. of responses/respondent	Avg. burden/response (in hrs.)	Total burden (in hrs.)
Georgia .....	409	1	0.75	307
California .....	325	1	0.75	244
Michigan .....	164	1	0.50	82
New Mexico .....	83	1	0.75	62
Arizona .....	283	1	0.75	212
Colorado .....	168	1	0.75	126
Connecticut .....	213	1	0.75	160
Delaware .....	202	1	0.50	101
Florida .....	261	1	0.50	131
So. Carolina .....	206	1	0.50	103
New Jersey .....	224	1	0.75	168
Washington .....	146	1	0.75	110
Total .....				1,806

The cost to the federal government of the SHAS project component of the HIV/AIDS Cooperative Agreement is approximately \$1.85 million.

2. Assessment of the Training Needs of Clinical and Environmental Laboratories—New—The National Laboratory Training Network (NLTN) was established in 1989 through a cooperative agreement between the Centers for Disease Control and Prevention (CDC) and the Association of State and Territorial Public Health Laboratory Directors (ASTPHLD). Its mission is to enhance the quality of laboratory testing in the nation's laboratories by providing training necessary for laboratory staff to improve their knowledge and skills in all aspects of the testing process. To accomplish this mission, seven NLTN offices were established at various sites throughout the nation giving all states and

territories access to laboratory training through this Network.

NLTN staff was charged with (1) assessing the training needs (2) developing programs, (3) delivering training and, (4) evaluating the effectiveness of the training. Staff in the seven offices must meet unique needs in the geographical area for which they are responsible. Assessing need is particularly important because more than 100,000 laboratories are doing 16,380 different tests of 631 analytes. NLTN staff must determine the most efficient and effective means to provide training where the greatest need exists.

Need for training in laboratories may be dependent on where the laboratories are located and what population they serve. For example, small laboratories in physicians' offices (POLs) may have very different needs than large, independent laboratories, hospital or

state laboratories. Manufacturers develop different products for laboratories that test in high volumes and can afford very sophisticated equipment than for small laboratories that do a limited number of tests. Education and training of personnel in the laboratories also very considerably. Current training needs are vastly different for people who have complete bachelor's degrees in medical technology or a science and those who have no formal laboratory education.

This information collection request is for clearance of a bank of questions from which NLTN staff may periodically select certain ones to use in survey to assess needs - and for flexibility to develop questions in specified formats to address specific practices related to the many tests available. This will allow the NLTN to focus on the appropriate lab type, target audience and test.

Respondents	No. of respondents	No. of responses/respondent	Avg. burden/response (in hrs.)	Total burden (in hrs.)
Laboratory* .....	2,000	1	0.5	1,000
Total .....				1,000

\* These respondents will vary depending on the type of need assessment required by the laboratory. In total, we estimate conducting no more than 2,000 assessments.

The total cost to respondents is estimated at \$450,000.

Dated: February 28, 1996.

Wilma G. Johnson,

*Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention.*

[FR Doc. 96-5023 Filed 3-4-96; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 96N-0005]

#### Review of Infant Formula Nutrient Requirements; Announcement of Study; Request for Scientific Data and Information; Announcement of Open Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (FASEB) is about to begin a review of data on the nutritional needs of infants and to make recommendations on appropriate concentrations of nutrients in formulas for term infants. The Infant Formula Act of 1980 directed FDA to ensure the safety and nutritional quality of infant formulas. Nutrient specifications for infant formulas are codified under the regulations for food and human consumption that were most recently revised in 1985. This review by LSRO/FASEB was requested by the agency, and it is intended to provide FDA with an up-to-date review of the nutritional needs of infants and of how those needs should be reflected in the levels of nutrients in formulas for term infants. To assist in the preparation of its scientific report, LSRO/FASEB is inviting the submission of scientific data and information on this topic. In addition, LSRO/FASEB will provide an opportunity for oral presentations at an open meeting.

**DATES:** The LSRO will hold a 1-day public meeting on this topic on May 31, 1996. The meeting will begin at 9 a.m. Requests to make oral presentations at the open meeting must be submitted in writing and received by May 10, 1996. Written presentations of scientific data, information, and views should be submitted on or before May 31, 1996.

**ADDRESSES:** Submit written requests to make oral presentations of scientific

data, information, and views at the open meeting to Sue Ann Anderson, Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD 20814, 301-530-7030, and to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Two copies of the scientific data, information, and views should be submitted to each office.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth A. Yetley, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4168.

**SUPPLEMENTARY INFORMATION:** FDA has a contract (223-92-2185) with FASEB concerning the analysis of scientific issues that bear on the safety of foods and cosmetics. The objectives of this contract are to provide information to FDA on general and specific issues of scientific fact associated with the analysis of human nutrition.

The Infant Formula Act of 1980 (Pub. L. 96-359) directed that FDA ensure the safety and nutritional quality of infant formulas. Regulations for infant formulas are codified in part 107 (21 CFR part 107) and include nutrient specifications for these products (§ 107.100). These nutrient specifications were last revised in 1985. In 1986, the infant formula provisions of the Federal Food, Drug, and Cosmetic Act (the act) were amended (Pub. L. 99-570). Among the changes that Congress made was to add the list of specifications to section 412(i)(1) of the act (21 U.S.C. 350a(i)(1)). The act also provides that the Secretary of Health and Human Services (and by delegation FDA) can revise this list by regulation (section 412(i)(2) of the act).

Since 1985, new data on nutritional needs of infants have accumulated from scientific investigations. In addition, a recommended dietary allowance (RDA) was set for selenium and estimated safe and adequate daily dietary intakes (ESADDI) were recommended for fluoride, chromium, and molybdenum by the National Research Council in 1989 (see Ref. 1). These four minerals are not included in the nutrient specifications for infant formulas in section 412(i) of the act or § 107.100.

FDA is announcing that it has asked FASEB, as a task under contract 223-92-2185, to provide FDA's Center for Food Safety and Applied Nutrition with an up-to-date review of nutritional needs of infants and of the resultant effects of new information about nutritional needs of infants on recommendations for levels of nutrients

in formulas for term infants. In response to this request, FASEB has directed its Life Sciences Research Office to obtain state-of-the-art scientific information on infant nutritional needs and related scientific questions on infant formula specifications. The LSRO/FASEB will undertake a study and prepare a documented scientific report that summarizes the available information related to these questions. LSRO has advised FDA that in preparing this report, it will consult with academic and medical experts and professional organizations concerned with nutritional needs of infants.

The objectives of this report will include evaluations of the following types of information: (1) New findings on nutrient requirements of infants and on any resultant need to establish or revise minimum and maximum amounts of nutrients required in formulas for term infants; (2) for macronutrients, evidence to support the addition of specific proteins (e.g., lactoferrin), carbohydrates (e.g., lactose), or fats (e.g., omega-3 fatty acids) to infant formulas; (3) information on the dietary essentiality of certain minerals (selenium, chromium, molybdenum, and fluoride), whether they should be included in infant formulas and, if so, at what levels; (4) scientific information on effects of ingestion of nucleotides, taurine, carnitine, urea, cholesterol, glutathione, and oligosaccharides; (5) information on differences in nutrient requirements of older infants (4 months of age and older) compared to infants younger than 4 months; (6) factors affecting nutrient stability and the product shelf life of infant formulas; and (7) the scientific basis for use of methods other than the protein efficiency ratio (PER) to ensure the quality of proteins used in infant formulas. A comprehensive final report that documents and summarizes the results of the evaluation will be prepared.

FDA and FASEB are announcing that LSRO/FASEB will hold a public meeting on this topic on May 31, 1996. The meeting will begin at 9 a.m. It is anticipated that the public meeting will be held for 1 day, depending on the number of requests to make oral presentations. Requests to make oral presentations at the open meeting must be submitted in writing and received by May 10, 1996. Written requests to make oral presentations of scientific data, information, and views at the open meeting should be submitted to LSRO/FASEB (address above) and to the Dockets Management Branch (HFA-305), Food and Drug Administration (address above). Two copies of the

material to be presented must be submitted to each office on or before the date of the open meeting.

FDA and LSRO/FASEB are also inviting submission of written presentations of scientific data, information, and views. These materials should be submitted on or before May 31, 1996. Two copies of the written materials must be submitted to both offices.

Under its contract with FDA, FASEB will provide the agency with a scientific report on or about March 31, 1997.

#### Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. National Research Council, "Recommended Dietary Allowances," 10th ed., Washington, DC, National Academy Press, 1989.

Dated: February 27, 1996.

William K. Hubbard,  
Associate Commissioner for Policy  
Coordination.

[FR Doc. 96-5117 Filed 3-4-96; 8:45 am]

BILLING CODE 4160-01-F

### Health Care Financing Administration

#### Notice of Hearing: Reconsideration of Disapproval of Pennsylvania State Plan Amendment (SPA)

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Notice of hearing.

**SUMMARY:** This notice announces an administrative hearing on April 10, 1996; 10:00 a.m. in Room 5020; 3535 Market Street, Philadelphia, Pennsylvania to reconsider our decision to disapprove Pennsylvania SPA 94-17.

**CLOSING DATE:** Requests to participate in the hearing as a party must be received by the presiding officer by March 20, 1996.

**FOR FURTHER INFORMATION CONTACT:** Stan Katz, Presiding Officer, HCFA, C1-04-27, 7500 Security Boulevard, Baltimore, Maryland 21224-1850, Telephone: (410) 786-2661.

**SUPPLEMENTARY INFORMATION:** This notice announces an administrative hearing to reconsider our decision to disapprove Pennsylvania State plan amendment (SPA) number 94-17.

Section 1116 of the Social Security Act (the Act) and 42 CFR, Part 430 establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a

State plan or plan amendment. The Health Care Financing Administration (HCFA) is required to publish a copy of the notice to a State Medicaid agency that informs the agency of the time and place of the hearing and the issues to be considered. If we subsequently notify the agency of additional issues that will be considered at the hearing, we will also publish that notice.

Any individual or group that wants to participate in the hearing as a party must petition the presiding officer within 15 days after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as amicus curiae must petition the presiding officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

Pennsylvania submitted SPA 94-17 for approval on December 29, 1995. The issues involved in this reconsideration are as follows: (1) The revised supplement submitted with SPA 94-17 provides for DSH payments to county nursing facilities prior to the proposed effective date of the plan amendment in violation of federal law at 42 CFR 447.256(c); (2) federal appropriations law, as interpreted by HCFA prohibit the "retroactive payment adjustments" which would be authorized under SPA 94-17; (3) the Department failed to publish adequate public notice in advance of the alleged change in its payment methods in accordance with the requirements at 42 CFR 447.205(c); and (4) the Department did not submit adequate information in support of its Medicare upper limit assurance at 42 CFR 447.272 and 447.253(b)(2).

In this plan amendment, the State of Pennsylvania revises significantly the State's nursing facility payment plan methodology to provide the formula for calculating a "disproportionate share" payment to county nursing facilities for State fiscal years (SFYs) 1993, 1994, and 1995.

These "disproportionate share" payments to county nursing facilities began in SFY 1991 and were continued in SFY 1992 under an approved State plan amendment. The State has revised significantly its nursing facility payment methodology three times since then (SFYs 1993, 1994 and 1995), but did not amend the State plan concerning these payments before the payments were made. Since Pennsylvania sought approval of a payment adjustment that was earlier than permissible under long-standing regulatory provisions

governing effective dates for plan amendments, HCFA disapproved the amendment.

#### Issue Regarding Effective Date of Payment Adjustments

Federal regulations at 42 CFR 447.256 specify that an approved state plan amendment becomes effective not earlier than the first day of the calendar quarter in which an approvable amendment is submitted. This amendment was submitted on December 29, 1994. Consequently, the *earliest* date for which Federal financial participation would be available for "disproportionate share" payments made under this amendment, if approved, was October 1, 1994. Even though this is the proposed effective date for SPA 94-17 requested by the State, this amendment could not be approved, as it would provide for retroactive "disproportionate share" payments for periods prior to the proposed effective date.

Pennsylvania's retroactive payment adjustments are also prohibited by the Department's appropriations law. The appropriations law provides that Medicaid payments may be made for any quarter with respect to state plan amendments which are in effect in that quarter, and which were submitted in, or prior to, that quarter and approved in that, or any later quarter. HCFA has interpreted this to mean that there can be no retroactive payments for any plan amendment which could result in an increase in Medicaid payments. If approved, this amendment would have increased Medicaid payments in quarters prior to the quarter in which the amendment was submitted; therefore, HCFA had no choice but to disapprove this SPA.

#### Issue Regarding Public Notice

Federal regulations provide that public notice of any significant proposed change in methods or standards for setting payment rates must be published before the proposed effective date of the change. Pennsylvania requested an effective date of October 1, 1994. However, the notice published on July 31, 1993, and relied on by the State to support the revised "disproportionate share" payments for SFY 1995, was defective. Even though the July 31, 1993, notice appears to be adequate for the SFY 1994 revised payment methodology, it is not sufficient for the SFY 1995 payment methodology because it did not contain an estimate of the expected increases in annual expenditures for SFY 1995, as required by Federal rules. Pennsylvania did not submit a plan amendment for

SFY 1995 payments in accordance with the effective date rules of 42 CFR 447.256(c). Therefore, the State's retroactive payment adjustments are not eligible for Federal financial participation.

While the State did publish notice of the SFY 1993 and 1994 adjustments, the State had indicated that public notice is not required because this amendment did not represent a significant change in the methods and standards for setting payment rates. HCFA disagreed. Since the State's currently approved plan provides for a nursing facility payment methodology for "disproportionate share" payments for SFYs 1991 and 1992 only, the State does not have methods or standards to presently authorize making such payments. Accordingly, the submission of this amendment, that established a new methodology in that a different percentage of medical assistance cost is used to determine the "disproportionate share" payments to county nursing facilities for SFYs 1993, 1994, and 1995, is a significant change for setting payment rates that must comply with the public notice requirements of 42 CFR 447.205(c).

#### Issue Regarding the Upper Limit

The State has not provided sufficient documentation in support of its assurance that the Medicare upper limit will not be exceeded because it did not incorporate the "disproportionate share" payments in the upper limit calculation. Pennsylvania was correct in stating that Federal law does not prohibit these payments; however, the State must establish that its payment rates, including these additional payments, meet the requirements of 42 CFR 447.253(b)(2) and 447.272. These two references state that aggregate Medicaid payments, to nursing facilities, will not exceed the amount that can reasonably be estimated to have been paid for those services under the Medicare payment principles.

#### Issue Regarding "Deemed Approval"

The State contends TN 94-17 was deemed approved by operation of law because it did not receive HCFA's request for additional information within 90 days of HCFA's receipt of the State's amendment. The applicable regulations at 42 CFR 447.256(b) state that if HCFA does not send notice to the State of its determination as to whether the assurances regarding a State plan amendment are acceptable within 90 days of the date HCFA receives the amendment, the assurances and the amendment will be deemed approved. In this case, the assurances and related

rate information were received by HCFA on January 3, 1995, making the 90th day April 3, 1995. As HCFA requested additional information regarding the proposed amendment by letter dated March 31, 1995, the 90-day requirement was met. The State's response, dated August 23, 1995, indicated that HCFA's request for additional information was postmarked April 5, 1995, and received on April 7, 1995. By letter dated September 19, 1995, the Philadelphia Regional Office notified the State that the 90-day requirement does not require that the State receive HCFA's response within 90 days. Because the Regional Office sent the response on March 31, 1995, it informed the State that the 90-day requirement had been met and that the amendment was not deemed approved.

The deficiencies described above allowed HCFA no choice but to recommend disapproval of Pennsylvania 94-17.

The notice to Pennsylvania announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Ms. Feather O. Houstoun,  
Secretary, Department of Public Welfare,  
Health and Welfare Building, P.O. Box  
2675, Harrisburg, Pennsylvania 17120

Dear Ms. Houstoun: I am responding to your request for reconsideration of the decision to disapprove Pennsylvania State Plan Amendment (SPA) 94-17.

Pennsylvania submitted SPA 94-17 for approval on December 29, 1994. The issues involved in this reconsideration are as follows: (1) the revised supplement submitted with SPA 94-17 provides for DSH payments to county nursing facilities prior to the proposed effective date of the plan amendment in violation of federal law at 42 CFR 447.256(c); (2) Federal appropriations law, as interpreted by HCFA prohibit the "retroactive payment adjustments" which would be authorized under SPA 94-17; (3) the State failed to publish adequate public notice in advance of the alleged change in its payment methods in accordance with the requirements at 42 CFR 447.205(c); and (4) the State did not submit adequate information in support of its Medicare upper limit assurance at 42 CFR 447.272 and 447.253(b)(2).

I am scheduling a hearing on your request for reconsideration to be held on April 10, 1996, on the Fifth Floor; Room 5020; 3535 Market Street; Philadelphia, Pennsylvania. If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed at 42 CFR Part 430.

I am designating Mr. Stanley Katz as the presiding officer. If these arrangements present any problems, please contact the presiding officer. In order to facilitate any communication which may be necessary between the parties to the hearing, please

notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing. The presiding officer may be reached at (410) 786-2661.

Sincerely,

Bruce C. Vladeck,  
Administrator.

(Section 1116 of the Social Security Act (42 U.S.C. section 1316); 42 CFR section 430.18) (Catalog of Federal Domestic Assistance Program No. 13.714, Medicaid Assistance Program)

Dated: February 23, 1996.

Bruce C. Vladeck,  
Administrator, Health Care Financing  
Administration.

[FR Doc. 96-5001 Filed 3-4-96; 8:45 am]

BILLING CODE 4120-01-P

## Health Resources and Services Administration

### Rural Health Research Centers; Availability of Funds

**AGENCY:** Health Resources and Services Administration (HRSA), HHS.

**ACTION:** Notice of availability of funds.

**SUMMARY:** The Office of Rural Health Policy (ORHP), Health Resources and Services Administration, announces that applications are being accepted for cooperative agreements to support Rural Health Research Centers. This program is authorized by Section 301, Title III, of the Public Health Service Act. These centers will conduct policy relevant research on rural health services issues of multi-state and national significance, and disseminate the findings of their research.

This program announcement for the above stated program is subject to the appropriation of funds. Applicants are advised that this program announcement is a contingency action being taken to assure that should funds become available for this purpose, awards can be made in a timely fashion consistent with the needs of the program. At this time, given a continuing resolution and the absence of FY 1996 appropriations for this program, the award of cooperative agreements cannot be assured and the amount of funds available cannot be estimated. Should funds become available, awards will be made to up to five Rural Health Research Centers for up to \$480,000 per center per year in total costs (direct plus indirect). The project period for these cooperative agreements is not to exceed 4 years, subject to the availability of funds. Should funds become available, notification of the total funding amount

available will be mailed to all persons who received application packets from the Grants Management Officer, c/o Global Exchange, Inc.

**DATES:** Applications must be received by the close of business May 31, 1996, to be considered for competition. Applications shall be considered as meeting the deadline if they are either (1) received on or before the deadline date; or (2) postmarked on or before the deadline date and received in time for submission to the review committee. A legibly dated receipt from a commercial carrier or U.S. Postal Service will be accepted in lieu of a postmark. Private metered postmarks will not be acceptable as proof of timely mailing. Applications not meeting the deadline will be returned to the applicant.

**ADDRESSES:** Requests for application packets and completed applications should be addressed to: The Grants Management Officer, c/o Global Exchange, Inc., 7910 Woodmont Avenue, Suite 400, Bethesda, Maryland 20814; tel: 1-800-784-0345; fax: 301-652-5264.

**FOR FURTHER INFORMATION CONTACT:** For information on program aspects, contact: Patricia Taylor, Ph.D., Office of Rural Health Policy, Room 9-05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-0835.

For information or technical assistance regarding business, budget, or financial issues contact: the Office of Grants Management, Bureau of Primary Health Care, Health Resources and Services Administration, 4350 East West Highway, 11th Floor, Bethesda, Maryland 20814, 301/594-4260.

The Standard Application Form and general instructions for competing applications, Form PHS 398 (revised 5/95) Public Health Service Grant, have been approved by the Office of Management and Budget (OMB No. 0925-0001). The narrative description of the research plan and the budget justification may not exceed a combined length of 30 pages.

#### **SUPPLEMENTARY INFORMATION:**

##### **Eligible Applicants**

All public and private entities, both non-profit and for-profit, are eligible to apply.

##### **Information Session for Prospective Applicants**

An information session for prospective applicants will be held at 10 a.m., Wednesday, April 3, 1996, in Room H, Parklawn Conference Center, Third Floor, Parklawn Building, 5600 Fishers Lane, Rockville MD. The information session will focus on the

programmatic and administrative details of the program. Also, questions from prospective applicants will be answered. A summary of this meeting will be available by faxed request to "Meeting Summary, RHRC Program," 301/443-2803.

##### **Applications**

Applicants should follow the instructions in Application Form PHS 398 where appropriate and the Supplemental Instructions where indicated. Applicants are strongly encouraged to obtain the application materials from the Grants Manager Officer, c/o Global Exchange, Inc., at the address above. This will assure that applicants have the complete application packet including the Supplemental Instructions.

##### **Notification**

In order to allow ORHP to plan for the Objective Review Process, applicants are encouraged to notify ORHP in writing of their intent to apply. This notification serves to inform ORHP of the anticipated number of applications which are being submitted. The address is: Patricia Taylor, Ph.D.; Office of Rural Health Policy; Health Resources and Services Administration; Parklawn Building Room 9-05; Rockville MD 20857. If notification is offered, it should be received by April 30, 1996.

##### **Program Objectives**

These awards will enable organizations to support research centers that conduct policy relevant research on rural health issues. Should funds become available, awards will be made for up to three general Rural Health Research Centers and up to two analytic Rural Health Research Centers for project periods not to exceed 4 years. These centers will be expected to (1) conduct policy relevant rural health services research and policy analyses and (2) disseminate their research findings and policy analyses to the rural health policy audience.

##### **Background**

The objective of the Rural Health Research Center cooperative agreement program is to increase the amount of high quality, policy relevant rural health services research and policy analysis being conducted in the nation. It is intended that the research and policy analysis reports of these centers will be useful to policy makers as they work to maintain and improve the availability, affordability and accessibility of health care services for rural residents.

The work carried out by each center will be multi-disciplinary, conducted

principally by social scientists in such disciplines as economics, organizational behavior, statistics, political science, sociology, and geography. Center staff may also include researchers from other relevant disciplines, for example, medicine, nursing, law and public health.

The general centers and analytic centers will have different emphases. The general Rural Health Research Centers will concentrate on rural health services research. Individual projects, which will generally require one to two years to complete, may include but are not limited to collection and analysis of new data, secondary analysis of existing data, comparative case studies, and evaluation of demonstration projects. These centers will be responsive to the diverse policy information needs of rural health policy makers in their multi-state regions as well as at the national level.

The analytic Rural Health Research Centers will concentrate on analytic policy studies that will be immediately useful in national policy development activities. These analyses, which will generally be completed in less than a year, will rely primarily on existing national data bases or synthesize findings from a variety of other studies to address national health policy issues affecting rural residents, communities and providers. These centers will have demonstrated capabilities in policy analysis, research methodologies, and data handling. In particular, they will have extensive experience with and access to large scale national data sets; and expertise in the linkage of and analyses across data sets.

In each year of the cooperative agreement, a center will be funded to carry out a number of research or policy analytic projects. These projects together constitute a center's research agenda or policy analysis agenda for the year. Each applicant's proposed research or policy analysis agenda should be well focused, preferably on no more than three clearly delineated areas of rural health services research or policy. Examples of focus areas include but are not limited to:

##### **Rural Health Care Financing/System Reform**

- Rural impact of Medicare, Medicaid and private insurer policies
- Rural impact of managed care, including managed care carve-outs, on access, cost and quality of health and mental health services
- Rural considerations in health care insurance, legislative, regulatory and other reforms

### Rural Systems Building

- Maintenance of health services capacity in rural communities through system development
- Development and operation of rural networks, managed care organizations, and provider sponsored organizations
- Alternative models for delivering health services, including alternative models for small rural hospitals

### Rural Health Professions Supply

- Financing
- Training
- Recruitment
- Retention
- Mid-level health care practitioners

### Meeting the Health Care Needs of Rural Populations

- Low income residents
- Racial and cultural groups
- Age groups (e.g., adolescents)
- Occupational groups (e.g., farm families)

Awards will be in the form of cooperative agreements. The ORHP involvement in the conduct of the cooperative agreements will generally include:

- Approval of key research staff
- Joint center/program staff participation in development of the center's annual agenda of research and policy analytic projects
- Possible center/program staff cooperation in study and survey designs
- Possible center/program staff cooperation in preparation and publication of results
- Joint center/program staff participation in designing strategies for dissemination of center reports to the rural health policy audience

### Healthy People 2000

The Health Resources and Services Administration urges applicants to submit proposed research agendas that address specific objectives of "Healthy People 2000." Potential applicants may obtain a copy of "Healthy People 2000" (Full Report; Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report; Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

### Review Procedures

Applications will be assessed for responsiveness to this notice. Any applications judged nonresponsive because they are incomplete, in an improper type size or exceed the specified page limit will be returned

without further consideration. All responsive applications will undergo objective review for scientific merit.

### Review Criteria for General Rural Health Research Centers

Grant applications for general rural health research centers will be evaluated on the basis of the following criteria:

1. The qualifications and achievements of the principal investigator, including level of productivity and quality of research on general and rural health services; record in use of research findings by health policy makers at state and national levels; record in timely completion of Department of Health and Human Services' funded health services research studies; experience in leading research teams; and appropriateness of time commitment. Expertise in Medicare and Medicaid is desirable.

2. The multi-disciplinary mix, number, qualifications and achievements of the senior personnel of the center, including level of productivity and quality of research on rural and general health services, demonstrated methodological skills, and experience in management and use of large data sets; record in use of their research findings by health policy makers at state and national levels; record in timely completion of U.S. Department of Health and Human Services' funded health services research studies; and appropriateness of their specific time commitments. Expertise in Medicare and Medicaid is desirable.

3. The quality of the organizational, physical and institutional arrangements to operate the proposed center, including computer facilities, access to large national data sets, and the availability of adequate space for routine interaction among the core research staff.

4. The planned level of commitment of the applicant institution to the proposed center including its specific plans to support research personnel and the organizational and management structure of the center.

5. The quality of the two individual research project proposals presented as part of this application.

6. The importance and relevance of the center's proposed Year One research agenda to rural health policy issues of multi-state and national concern, whether it is focused on no more than three clearly delineated substantive areas of rural health services, and degree to which it is a realistic and well conceived program in view of available skills and funding resources.

7. The appropriateness of the proposed budget.

### Review Criteria for Analytic Rural Health Research Centers

Grant applications for analytic rural health research centers will be evaluated on the basis of the following criteria:

1. The qualifications and achievements of the principal investigator, including level of productivity and quality of national health policy analyses on general and rural issues; experience in leading research teams; and appropriateness of time commitment. Expertise in Medicare, Medicaid and rural health policy is highly desirable.

2. The multi-disciplinary mix, number, qualifications and achievements of the senior personnel of the center, including level of productivity and quality of national health policy analyses and health services research on rural and general issues, expertise in Medicare, Medicaid and rural health policy, demonstrated methodological skills, experience in production of analytic reports suitable for professional and lay audiences, experience in management and use of large data sets, and expertise in the linkage of and analyses across data sets; and appropriateness of their specific time commitments.

3. The record of the applicant organization and the lead investigators in timely completion of health services research and policy analytic studies funded by the U.S. Department of Health and Human Services.

4. The quality of the organizational, physical and institutional arrangements to operate the proposed center, including computer facilities, access to large scale national data sets, and the availability of adequate space for routine interaction among the core research staff.

5. The quality of the two individual analytic policy study proposals presented as part of this application.

6. The importance and relevance of the center's proposed Year One agenda of analytic policy studies to rural health policy issues of national concern, whether it is focused on no more than three well delineated substantive areas of rural health policy, and the degree to which it is a realistic and well conceived program in view of available skills and funding resources.

7. The appropriateness of the proposed budget.

In awarding grants, geographic distribution of centers will be considered.

**Other Information**

The Rural Health Research Centers Grant Program has been determined to be a program which is not subject to the provisions of Executive Order 12372 concerning intergovernmental review of Federal programs.

The OMB Catalog of Federal Domestic Assistance number is 93.155.

Dated: February 29, 1996.

Ciro V. Sumaya,  
Administrator.

[FR Doc. 96-5113 Filed 3-4-96; 8:45 am]

BILLING CODE 4160-15-P

**National Institutes of Health****National Center for Human Genome Research; Notice of Closed Meeting**

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix), notice is hereby given of the following meeting:

*Name of Committee:* Human Genome Research Initial Review Group.

*Date:* March 18, 1996.

*Time:* 2:00-6:00 pm.

*Place:* Teleconference, NIH, Building 38A, Room 605, 9000 Rockville Pike, Bethesda, Maryland.

*Contact Person:* Ms. Linda Engel, Chief, Office of Scientific Review, National Center for Human Genome Research, National Institutes of Health, Building 38A, Room 604, Bethesda, Maryland 20892, (301) 402-0838.

*Purpose/Agenda:* To review and evaluate grant applications and/or contract proposals. The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. The applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. (Catalog of Federal Domestic Assistance Program No. 93.172, Human Genome Research)

Dated: February 28, 1996.

Susan K. Feldman,

*Committee Management Officer, NIH.*

[FR Doc. 96-5019 Filed 3-4-96; 8:45 am]

BILLING CODE 4140-01-M

**National Institute of Nursing Research; Notice of Closed Meeting**

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting:

*Name of Committee:* Nursing Science Review Committee.

*Date:* March 14-15, 1996.

*Time:* 8:30 a.m. until adjournment.

*Place:* Holiday Inn Chevy Chase, Chase Meeting Room, 5520 Wisconsin Avenue, Bethesda, Maryland 20815.

*Contact Person:* Dr. Mary Stephens-Frazier, 9000 Rockville Pike, Building 45, Room 3AN.12, Bethesda, Maryland 20892, (301) 594-5971.

*Purpose/Agenda:* To review and evaluate grant applications.

The meeting will be closed in accordance with the provisions set forth in secs. 552(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than fifteen days prior to the meeting due to the partial shutdown of the Federal Government and urgent need to meet timing limitations imposed by the grant review cycle.

(Catalog of Federal Domestic Assistance Programs No. 93.361, Nursing Research, National Institutes of Health.)

Dated: February 27, 1996.

Susan K. Feldman,

*Committee Management Officer, NIH.*

[FR Doc. 96-5018 Filed 3-4-96; 8:45 am]

BILLING CODE 4140-01-M

**National Institute of Environmental Health Sciences; Notice of a Closed Meeting**

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Environmental Health Sciences Special Emphasis Panel (SEP) meeting:

*Name of SEP:* Endocrine Disrupting Chemicals and Women's Health Outcomes (RFA-96-003).

*Date:* March 19-21, 1996.

*Time:* 8:00 P.M.

*Place:* (3/19/96) Omni Europa Hotel, Research Triangle Park, NC. (3/20-21/96) NIEHS, South Campus Building 101-C, Research Triangle Park, NC.

*Contact Person:* Dr. Carol Shreffler, National Institute of Environmental Health Sciences, P.O. Box 12233, Research Triangle Park, NC 27709, (919) 541-1445.

*Purpose/Agenda:* To review and evaluate grant applications.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than fifteen days prior to this meeting due to the

urgent need to meet timing limitations imposed by the grant review cycle.

(Catalog of Federal Domestic Assistance Programs Nos. 93.113, Biological Response to Environmental Agents; 93.114, Applied Toxicological Research and Testing; 93.115, Biometry and Risk Estimation; 93.894, Resource and Manpower Development, National Institutes of Health.)

Dated: February 28, 1996.

Susan K. Feldman,

*Committee Management Officer, NIH.*

[FR Doc. 96-5114 Filed 3-4-96; 8:45 am]

BILLING CODE 4140-01-M

**National Institute of Mental Health; Notice of Closed Meeting**

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting of the National Institute of Mental Health Special Emphasis Panel:

*Agenda/Purpose:* To review and evaluate grant applications.

*Committee Name:* National Institute of Mental Health Special Emphasis Panel.

*Date:* March 21, 1996.

*Time:* 10 a.m.

*Place:* Georgetown Holiday Inn, 2101 Wisconsin Avenue, N.W., Washington, DC 20007.

*Contact Person:* Donna Ricketts, Parklawn, Room 9-101, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301-443-3936.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. (Catalog of Federal Domestic Assistance Program Numbers 93.242, 93.281, 93.282).

Dated: February 28, 1996.

Susan K. Feldman,

*Committee Management Officer, NIH.*

[FR Doc. 96-5115 Filed 3-4-96; 8:45 am]

BILLING CODE 4140-01-M

**Substance Abuse and Mental Health Services Administration****Cosponsorship of the Caring for Every Child's Mental Health: Communities Together Campaign**

**AGENCY:** Center for Mental Health Services, Substance Abuse and Mental Health Services Administration, HHS.

**ACTION:** Notice of opportunity for cosponsorship.

**SUMMARY:** The Center for Mental Health Services (CMHS), a component of the

Substance Abuse and Mental Health Services Administration (SAMHSA), announces the opportunity for for-profit and nonprofit organizations to cosponsor the Caring for Every Child's Mental Health: Communities Together Campaign.

**DATES:** To receive consideration, requests to participate as a cosponsor must be received by Ms. Charlotte Mehuron, Director, Office of External Liaison, CMHS, Parklawn Building, Room 13-103, 5600 Fishers Lane, Rockville, Maryland 20857; Fax (301) 443-5163. There are no deadlines applicable to this cosponsorship opportunity.

**FOR FURTHER INFORMATION CONTACT:** Ms. Valna Montgomery, Project Officer, Office of External Liaison, CMHS, Parklawn Building, Room 13-103, 5600 Fishers Lane, Rockville, Maryland 20857; (301) 443-2792.

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

America's young people are at risk, and they desperately need the Nation's attention. Preliminary studies suggest that, at any given time, at least one in five children and adolescents may have behavioral, emotional, or mental health problems that, without help, can lead to school failure, alcohol and other drug use, family discord, or violence. At least 1 in 20—or as many as 3 million young people—may have a serious emotional disturbance that disrupts his or her ability to function. Tragically, an estimated two-thirds of all these young people are not getting the help they need.

Recognizing the need for increased national awareness of and support for children and adolescents with mental health problems and their families, the CMHS initiated a 4-year national education campaign in October 1994. The campaign, Caring for Every Child's Mental Health: Communities Together, hereinafter called Children's Campaign, is managed by the CMHS Office of External Liaison in collaboration with the Child, Adolescent and Family Branch, Division of Demonstration Programs, CMHS. CMHS is also collaborating with the National Institute of Mental Health, a component of the National Institutes of Health (NIH) and the Maternal and Child Health Bureau in the Health Resources and Services Administration (HRSA). SAMHSA, HRSA, and NIH are agencies in the U.S. Department of Health and Human Services.

The goals of the Children's Campaign are to: (1) Increase public awareness that the mental health of every child and

adolescent is as important as physical health; (2) help families, educators, health care and social service professionals, and others recognize mental health problems in children and adolescents, and seek appropriate intervention and services early; (3) diminish the stigma associated with mental health problems; (4) assist and support the Comprehensive Community Mental Health Services for Children Program grantees with their community-based education; and (5) nationally disseminate knowledge gained from model programs and science-based research.

##### **Requirements of Cosponsorship**

The Children's Campaign is seeking partnership with one or more public and private for-profit and nonprofit organizations to develop and distribute information to effectively impart the Children's Campaign messages to target groups, such as children and adolescents and their families; teachers, counselors, and principals; youth organizations; primary care providers and mental health care professionals; government agencies; community organizations; and the general public. The Campaign messages are:

- Every child's mental health is important.
- Many children have mental health problems.
- These problems are real and painful and can be recognized and treated.
- Caring families and communities working together can help.
- Information is available; call (800) 789-2647.

CMHS will reserve the right to determine the form and content of the information provided to the target groups. We envision cosponsorship with a wide variety of organizations concerned about children and adolescents with mental health problems and their families in the development and dissemination of information. The duties of the cosponsors may include such activities as implementation of an information campaign for dissemination of the Children's Campaign messages, including but not limited to, printing brochures or booklets; production of public service announcements or videos; press briefings and media events; and production and distribution of other materials, such as posters, flyers, paid advertising, and an exhibit designed for young people, families, educators or health care providers.

##### **Availability of Funds**

There are no Federal funds available to conduct the cosponsored activities for

the Children's Campaign. It will be the unilateral responsibility of the cosponsor(s) to bear all costs.

##### **Eligibility of Cosponsorship**

To be eligible, an interested party must be: (1) A public or private nonprofit or for-profit organization or corporation and (2) an entity that, by virtue of its nature and purpose, has a legitimate interest in the target groups.

##### **Expression of Interest**

Each request for cosponsorship should be in writing and contain information pertinent to the cosponsorship opportunity.

##### **Evaluation Criteria**

The cosponsors will be selected by the Children's Campaign management staff, CMHS, based on the following evaluation criteria: (1) The qualifications and capability of the interested party to develop and produce materials for dissemination of the Children's Campaign messages to the target population, and (2) the ability of the interested party to arrange for funding for development and dissemination of Children's Campaign information materials or messages.

Neither this notice nor actions pursuant thereto, creates a proprietary right or right of any kind in any natural or artificial person requesting cosponsorship. CMHS has the unilateral right to refuse to enter into a cosponsorship arrangement with any entity; exercise of this right is solely within the discretion of CMHS.

##### **Other Information**

Prior to the selection of the cosponsors, the Children's Campaign staff will meet separately with interested parties who best meet the evaluation criteria. In situations where the Food and Drug Administration (FDA) regulates the labeling of products manufactured by cosponsors, the inclusion of the Children's Campaign logo on such products will be subject to FDA review and may require agency authorization, depending on how and the context in which the logo is to be used. Moreover, other Federal agencies may be involved in the cosponsorship process. Furthermore, as a general rule, restrictions will apply to the use of the Children's Campaign logo or other indicia, to avoid suggestions that DHHS, or any other department or agency of the Federal Government, endorses any of the products involved in the Children's Campaign. Once details of the program have been mutually agreed upon, cosponsors will be required to enter into a cosponsorship agreement with the



CMHS setting forth the rights and responsibilities of the cosponsor and CMHS, especially the right of CMHS to approve the Children's Campaign messages and use of the Campaign logo.

Dated: February 29, 1996.

Richard Kopanda,

*Acting Executive Officer, SAMHSA.*

[FR Doc. 96-5119 Filed 3-4-96; 8:45 am]

BILLING CODE 4162-20-P

### **Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies, and Laboratories That Have Withdrawn From the Program**

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS (Formerly: National Institute on Drug Abuse, ADAMHA, HHS).

**ACTION:** Notice.

**SUMMARY:** The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or revoked, the laboratory will be omitted from updated lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be identified as such at the end of the current list of certified laboratories, and will be omitted from the monthly listing thereafter.

**FOR FURTHER INFORMATION CONTACT:** Mrs. Giselle Hersh, Division of Workplace Programs, Room 13A-54, 5600 Fishers Lane, Rockville, Maryland 20857; Tel.: (301) 443-6014.

**SUPPLEMENTARY INFORMATION:** Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100-71. Subpart C of the Guidelines, "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an

on-site inspection. To maintain that certification a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Guidelines, the following laboratories meet the minimum standards set forth in the Guidelines:

Aegis Analytical Laboratories, Inc., 624 Grassmere Park Rd., Suite 21, Nashville, TN 37211, 615-331-5300  
Alabama Reference Laboratories, Inc., 543 South Hull St., Montgomery, AL 36103, 800-541-4931/205-263-5745  
American Medical Laboratories, Inc., 14225 Newbrook Dr., Chantilly, VA 22021, 703-802-6900  
Associated Pathologists Laboratories, Inc., 4230 South Burnham Ave., Suite 250, Las Vegas, NV 89119-5412, 702-733-7866  
Associated Regional and University Pathologists, Inc. (ARUP), 500 Chipeta Way, Salt Lake City, UT 84108, 801-583-2787  
Baptist Medical Center—Toxicology Laboratory, 9601 I-630, Exit 7, Little Rock, AR 72205-7299, 501-227-2783 (formerly: Forensic Toxicology Laboratory Baptist Medical Center)  
Bayshore Clinical Laboratory, 4555 W. Schroeder Dr., Brown Deer, WI 53223, 414-355-4444/800-877-7016  
Cedars Medical Center, Department of Pathology, 1400 Northwest 12th Ave., Miami, FL 33136, 305-325-5810  
Centinela Hospital Airport Toxicology Laboratory, 9601 S. Sepulveda Blvd., Los Angeles, CA 90045, 310-215-6020  
Clinical Reference Lab, 11850 West 85th St., Lenexa, KS 66214, 800-445-6917  
CompuChem Laboratories, Inc., 3308 Chapel Hill/Nelson Hwy., Research Triangle Park, NC 27709, 919-549-8263/800-833-3984 (Formerly: CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory, Roche CompuChem Laboratories, Inc., A Member of the Roche Group)  
CORNING Clinical Laboratories, 4771 Regent Blvd., Irving, TX 75063, 800-526-0947 (formerly: Damon Clinical Laboratories, Damon/MetPath)  
CORNING Clinical Laboratories, 875 Greentree Rd., 4 Parkway Ctr., Pittsburgh, PA 15220-3610, 800-284-7515 (formerly: Med-Chek Laboratories, Inc., Med-Chek/Damon, MetPath Laboratories)  
CORNING Clinical Laboratories, 24451 Telegraph Rd., Southfield, MI 48034, 800-444-0106 ext. 650 (formerly: HealthCare/Preferred Laboratories, HealthCare/MetPath)  
CORNING Clinical Laboratories Inc., 1355 Mittel Blvd., Wood Dale, IL 60191, 708-

595-3888 (formerly: MetPath, Inc., CORNING MetPath Clinical Laboratories)  
CORNING Clinical Laboratories, South Central Division, 2320 Schuetz Rd., St. Louis, MO 63146, 800-288-7293 (formerly: Metropolitan Reference Laboratories, Inc.)  
CORNING Clinical Laboratory, One Malcolm Ave., Teterboro, NJ 07608, 201-393-5000 (formerly: MetPath, Inc., CORNING MetPath Clinical Laboratories)  
CORNING National Center for Forensic Science, 1901 Sulphur Spring Rd., Baltimore, MD 21227, 410-536-1485 (formerly: Maryland Medical Laboratory, Inc., National Center for Forensic Science)  
CORNING Nichols Institute, 7470-A Mission Valley Rd., San Diego, CA 92108-4406, 800-446-4728/619-686-3200 (formerly: Nichols Institute, Nichols Institute Substance Abuse Testing (NISAT))  
Cox Medical Centers, Department of Toxicology, 1423 North Jefferson Ave., Springfield, MO 65802, 800-876-3652/417-836-3093  
Dept. of the Navy, Navy Drug Screening Laboratory, Great Lakes, IL, Building 38-H, Great Lakes, IL 60088-5223, 708-688-2045/708-688-4171  
Diagnostic Services Inc., dba DSI, 4048 Evans Ave., Suite 301, Fort Myers, FL 33901, 813-936-5446/800-735-5416  
Doctors Laboratory, Inc., P.O. Box 2658, 2906 Julia Dr., Valdosta, GA 31604, 912-244-4468.  
DrugProof, Division of Dynacare/Laboratory of Pathology, LLC, 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 800-898-0180/206-386-2672 (formerly: Laboratory of Pathology of Seattle, Inc., DrugProof, Division of Laboratory of Pathology of Seattle, Inc.)  
DrugScan, Inc., P.O. Box 2969, 1119 Mearns Rd., Warminster, PA 18974, 215-674-9310  
ElSohly Laboratories, Inc., 5 Industrial Park Dr., Oxford, MS 38655, 601-236-2609  
General Medical Laboratories, 36 South Brooks St., Madison, WI 53715, 608-267-6267  
Harrison Laboratories, Inc., 9930 W. Highway 80, Midland, TX 79706, 800-725-3784/915-563-3300 (formerly: Harrison & Associates Forensic Laboratories)  
Holmes Regional Medical Center Toxicology Laboratory, 5200 Babcock St., N.E., Suite 107, Palm Bay, FL 32905, 407-726-9920  
Jewish Hospital of Cincinnati, Inc., 3200 Burnet Ave., Cincinnati, OH 45229, 513-569-2051  
LabOne, Inc., 8915 Lenexa Dr., Overland Park, Kansas 66214, 913-888-3927 (formerly: Center for Laboratory Services, a Division of LabOne, Inc.),  
Laboratory Corporation of America, 13900 Park Center Rd., Herndon, VA 22071, 703-742-3100 (Formerly: National Health Laboratories Incorporated)  
Laboratory Corporation of America, 21903 68th Ave. South, Kent, WA 98032, 206-395-4000 (Formerly: Regional Toxicology Services)  
Laboratory Corporation of America Holdings, 1120 Stateline Rd., Southaven, MS 38671, 601-342-1286 (Formerly: Roche Biomedical Laboratories, Inc.)  
Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 800-437-

4986 (Formerly: Roche Biomedical Laboratories, Inc.)  
 Laboratory Specialists, Inc., 113 Jarrell Dr., Belle Chasse, LA 70037, 504-392-7961  
 Marshfield Laboratories, 1000 North Oak Ave., Marshfield, WI 54449, 715-389-3734/800-222-5835  
 MedExpress/National Laboratory Center, 4022 Willow Lake Blvd., Memphis, TN 38175, 901-795-1515  
 Medical College Hospitals Toxicology Laboratory, Department of Pathology, 3000 Arlington Ave., Toledo, OH 43699-0008, 419-381-5213  
 Medlab Clinical Testing, Inc., 212 Cherry Lane, New Castle, DE 19720, 302-655-5227  
 MedTox Laboratories, Inc., 402 W. County Rd. D, St. Paul, MN 55112, 800-832-3244/612-636-7466  
 Methodist Hospital of Indiana, Inc., Department of Pathology and Laboratory Medicine, 1701 N. Senate Blvd., Indianapolis, IN 46202, 317-929-3587  
 Methodist Medical Center Toxicology Laboratory, 221 N.E. Glen Oak Ave., Peoria, IL 61636, 800-752-1835/309-671-5199  
 MetroLab-Legacy Laboratory Services, 235 N. Graham St., Portland, OR 97227, 503-413-4512, 800-237-7808(x4512)  
 National Psychopharmacology Laboratory, Inc., 9320 Park W. Blvd., Knoxville, TN 37923, 800-251-9492  
 National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 805-322-4250  
 Northwest Toxicology, Inc., 1141 E. 3900 South, Salt Lake City, UT 84124, 800-322-3361  
 Oregon Medical Laboratories, P.O. Box 972, 722 East 11th Ave., Eugene, OR 97440-0972, 503-687-2134  
 Pathology Associates Medical Laboratories, East 11604 Indiana, Spokane, WA 99206, 509-926-2400  
 PDLA, Inc. (Princeton), 100 Corporate Court, So. Plainfield, NJ 07080, 908-769-8500/800-237-7352  
 PharmChem Laboratories, Inc., 1505-A O'Brien Dr., Menlo Park, CA 94025, 415-328-6200/800-446-5177  
 PharmChem Laboratories, Inc., Texas Division, 7606 Pebble Dr., Fort Worth, TX 76118, 817-595-0294 (formerly: Harris Medical Laboratory)  
 Physicians Reference Laboratory, 7800 West 110th St., Overland Park, KS 66210, 913-338-4070/800-821-3627  
 Poisonlab, Inc., 7272 Clairemont Mesa Rd., San Diego, CA 92111, 619-279-2600/800-882-7272  
 Premier Analytical Laboratories, 15201 I-10 East, Suite 125, Channelview, TX 77530, 713-457-3784 (formerly: Drug Labs of Texas)  
 Presbyterian Laboratory Services, 1851 East Third Street, Charlotte, NC 28204, 800-473-6640  
 Puckett Laboratory, 4200 Mamie St., Hattiesburg, MS 39402, 601-264-3856/800-844-8378  
 Scientific Testing Laboratories, Inc., 463 Southlake Blvd., Richmond, VA 23236, 804-378-9130

Scott & White Drug Testing Laboratory, 600 S. 25th St., Temple, TX 76704, 800-749-3788  
 S.E.D. Medical Laboratories, 500 Walter NE, Suite 500, Albuquerque, NM 87102, 505-244-8800, 800-999-LABS  
 Sierra Nevada Laboratories, Inc., 888 Willow St., Reno, NV 89502, 800-648-5472  
 SmithKline Beecham Clinical Laboratories, 7600 Tyrone Ave., Van Nuys, CA 91045, 818-989-2520  
 SmithKline Beecham Clinical Laboratories, 801 East Dixie Ave., Leesburg, FL 34748, 904-787-9006 (formerly: Doctors & Physicians Laboratory)  
 SmithKline Beecham Clinical Laboratories, 3175 Presidential Dr., Atlanta, GA 30340, 770-452-1590 (formerly: SmithKline Bio-Science Laboratories)  
 SmithKline Beecham Clinical Laboratories, 506 E. State Pkwy., Schaumburg, IL 60173, 708-885-2010 (formerly: International Toxicology Laboratories)  
 SmithKline Beecham Clinical Laboratories, 400 Egypt Rd., Norristown, PA 19403, 800-523-5447 (formerly: SmithKline Bio-Science Laboratories)  
 SmithKline Beecham Clinical Laboratories, 8000 Sovereign Row, Dallas, TX 75247, 214-638-1301 (formerly: SmithKline Bio-Science Laboratories)  
 SmithKline Beecham Clinical Laboratories, 1737 Airport Way South, Suite 200, Seattle, WA 98134, 206-623-8100  
 South Bend Medical Foundation, Inc., 530 N. Lafayette Blvd., South Bend, IN 46601, 219-234-4176  
 Southwest Laboratories, 2727 W. Baseline Rd., Suite 6, Tempe, AZ 85283, 602-438-8507  
 St. Anthony Hospital (Toxicology Laboratory), P.O. Box 205, 1000 N. Lee St., Oklahoma City, OK 73102, 405-272-7052  
 Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 2703 Clark Lane, Suite B, Lower Level, Columbia, MO 65202, 314-882-1273  
 Toxicology Testing Service, Inc., 5426 N.W. 79th Ave., Miami, FL 33166, 305-593-2260  
 TOXWORX Laboratories, Inc., 6160 Variel Ave., Woodland Hills, CA 91367, 818-226-4373 (formerly: Laboratory Specialists, Inc.; Abused Drug Laboratories; MedTox Bio-Analytical, a Division of MedTox Laboratories, Inc.)  
 UNILAB, 18408 Oxnard St., Tarzana, CA 91356, 800-492-0800/818-343-8191 (formerly: MetWest-BPL Toxicology Laboratory),

No laboratories withdrew from the Program during February 1996.

Richard Kopanda,

*Acting Executive Officer, Substance Abuse and Mental Health Services Administration.*

[FR Doc. 96-5132 Filed 3-4-96; 8:45 am]

BILLING CODE 4160-20-U

## ADVISORY COMMISSION ON INTERGOVERNMENTAL RELATIONS

### Notice of Public Hearing Postponement and Extended Comment Period

Due to scheduling conflicts and other issues prohibiting the participation of several commissioners, the Advisory Commission on Intergovernmental Relations (ACIR) has postponed the scheduled March 8 public hearing on the preliminary report, *The Role of Federal Mandates in Intergovernmental Relations* until Tuesday, March 26, 1996. The exact time and location of the rescheduled hearing will be announced as soon as the information is available.

In addition, ACIR is extending the public comment period on the preliminary report until Friday, March 29, 1996.

#### FOR FURTHER INFORMATION CONTACT:

Advisory Commission on Intergovernmental Relations, 800 K Street, NW, Suite 450, South Tower, Washington, DC 20575. Phone: (202) 653-5540/FAX: (202) 653-5429/Internet: ir002529@interramp.com.

Dated: March 1, 1996.

William E. Davis,  
*Executive Director.*

[FR Doc. 96-5252 Filed 3-4-96; 8:45 am]

BILLING CODE 5500-01-M

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[WO-320-4130-02-24 1A]

### Notice of Proposed Information Collection

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, the Bureau of Land Management (BLM) is announcing its intention to request approval for the collection of information from mining claimants and operators conducting activities on the Public Lands under the authority of the mining laws. The purpose of the collection is to prevent unnecessary or undue degradation and prevent impairment of wilderness suitability as required by Sections 302(b) and 603(c) the Federal Land Policy and Management Act.

**DATES:** Comments on the proposed information collection must be received by May 6, 1996 to be assured of consideration.

**ADDRESSES:** Comments may be mailed to: Regulatory Management Team (420), Bureau of Land Management, 1849 C Street NW, Room 401LS, Washington, DC 20240.

Comments may be sent via Internet to: WO140@attmail.com. Please include "ATTN: Surface Management" and your name and return address in your Internet message.

Comments may be hand-delivered to the Bureau of Land Management Administrative Record, Room 401, 1620 L Street, NW, Washington, DC.

Comments will be available for public review at the L Street address during regular business hours (7:45 A.M. to 4:15 p.m.), Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Richard E. Deery, (202) 452-0353.

**SUPPLEMENTARY INFORMATION:** In accordance with 5 CFR 1320.8(d), BLM is required to provide 60-day notice in the Federal Register concerning a proposed collection of information to solicit comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Accordingly, BLM will not require any of the information proposed to be collected as described below until it receives and analyzes any comments and obtains approval from the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*, and OMB assigns a clearance number.

In 1980, the BLM published two final rules to establish procedures for managing prospecting, exploration, mining and processing activities on lands subject to the operation of the mining law (45 FR 13974, March 3, 1980 and 45 FR 78902, November 26, 1980). The two rule makings put into place the regulations at 43 C.F.R. Subpart 3802 (Exploration and Mining, Wilderness Review Program) and Subpart 3809 (Surface Management). The principal authorities for these two sets of regulations are the mining law (30 U.S.C. 22 *et seq.*) and the Federal Land Policy and Management Act of 1976 (43

U.S.C. 1701 *et seq.*). OMB approved the information collections contained in these regulations and assigned OMB clearance numbers 1004-0110 (34 C.F.R. 3802) and 1004-0104 (43 C.F.R. 3809).

BLM and the public generally refer to the two sets of regulations as the "surface management" regulations. Under the terms of these rules, anyone planning to conduct activities the public lands under the mining law must submit various types of information to the BLM to obtain a benefit: use of the public lands to prospect, explore, develop, mine, or process Federally owned mineral resources pursuant to the mining law. Depending on the lands involved in the activity, the mining claimant or operator must submit the information in either a Notice (43 C.F.R. 3809.1-3) or a Plan of Operations (43 C.F.R. 3802.1-4 and 3809.1-5). Casual use activities require no submission of information to the BLM in either set of regulations. For the convenience of the public, BLM proposes to treat both rules in a single information collection approval. Consolidation of the information collection burden is appropriate because on several occasions, activities regulated under both sets of regulations have been embraced by a single mineral property under the control of a single operator.

The types of information generally contained within each type of response include: (1) The mining claimant or operator's name, address and phone number; (2) the activity's location; (3) when available, the mining claim recordation number(s); (4) the methods and equipment to be employed during the operations; (5) a description of the proposed activity sufficient to locate it on the ground; (6) a description of reclamation or mitigation measures to be employed to prevent unnecessary or undue degradation; (7) a description of location of aircraft landing areas; (8) a description of access routes and equipment used in construction; and (9) a description of measures to be taken during periods of non-operation. In addition to the project information, various types of financial information, financial instruments and forms associated with bonding and financial guarantees required to ensure reclamation will be required under pending modifications of 43 C.F.R. 3809. For details on these requirements, see the proposed bonding regulations at 56 FR 31602, published on July 11, 1991.

When mining claimants or operators propose to conduct mineral development operations on the public lands, they may have to submit information to State agencies as well.

Prior to the promulgation of the surface management regulations, relatively robust State programs were developed in most of the western States. In recognition of these programs, the regulations explicitly allow for the creation, by memorandums of agreement, of joint State/Federal programs for administration and enforcement of the regulations. Thus, in addition to the information noted above, any information currently required by State mining or reclamation laws and regulations for a permit or other approval to conduct exploration or mining operations is to be submitted BLM and the appropriate State agency.

When the required information is properly filed, BLM uses the information to determine if the proposed activities will prevent unnecessary or undue degradation of the public lands. If lands under wilderness review are involved, BLM will also make a determination regarding the prevention of wilderness impairment. In the latter case, a determination that impairment may occur will result in the rejection of the proposed plan. In the case where there is no land under wilderness review, BLM will either approve a plan as submitted if it prevents unnecessary or undue degradation or modify it to prevent unnecessary or undue degradation. In making both of these determinations, BLM makes use of the National Environmental Policy Act (NEPA) process.

For Notice level actions, the information submitted by the respondent is subject to review by BLM field staff, but no BLM approval is necessary. BLM will examine any activity that may result in unnecessary or undue degradation. In the event an activity may result in unnecessary or undue degradation, BLM will advise the respondent not to undertake that activity unless it is modified to eliminate the conflict. Road construction resulting in inside cuts greater than three feet can prompt a consultation requirement if the BLM decides such consultation is necessary.

Based on BLM's experience administering the surface management program over the past 15 years, the public reporting burden for this entire collection is estimated to average 15 hours per response. The respondents are mining claimants and operators of prospecting, exploration, mining, and processing operations. The number of responses per respondent is one per operation, and most responses are generally sufficient for several year's worth of proposed activities. The number of responses per year is

estimated to be about 1,300. The estimated total annual burden on new respondents is collectively 19,500 hours.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will also become a matter of public record.

Dated: February 28, 1996.

Annetta L. Cheek,

*Regulatory Management Team.*

[FR Doc. 96-4993 Filed 3-4-96; 8:45 am]

BILLING CODE 4310-84-P

[WO-310-1310-01-24 1A]

### **Extension of Currently Approved Information Collection; OMB Approval Number 1004-0162**

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, the Bureau of Land Management (BLM) is announcing its intention to request extension of approval for the collection of information from those persons who: (1) Submit a notice of intent (Form 3150-4) to conduct oil and gas geophysical exploration operations on Federal lands, and (2) submit a notice of completion (Form 3150-5) of oil and gas exploration operations. BLM uses the information to determine who is conducting geophysical operations on public lands and to ensure that appropriate measures are taken to protect the environment as required by the National Environmental Policy Act of 1969.

**DATE:** Comments on the proposed information collection must be received by May 6, 1996 to be considered.

**ADDRESSES:** Comments may be mailed to: Regulatory Management Team (420), Bureau of Land Management, 1849 C. Street NW, Room 401 LS Bldg., Washington, D.C. 20240.

Comments may be sent via Internet to: WO140@attmail.com. Please include "Attn: 1004-0162" and your name and return address in your Internet message.

Comments may be hand delivered to the Bureau of Land Management Administrative Record, Room 401, L Street, NW, Washington, D.C.

Comments will be available for public review at the L Street address during regular business hours (7:45 A.M. to 4:15 P.M., Monday through Friday).

**FOR FURTHER INFORMATION CONTACT:** Gloria J. Austin, (202) 452-0340.

**SUPPLEMENTARY INFORMATION:** In accordance with 5 CFR 1320.8(d), BLM is required to provide 60-day notice in the Federal Register concerning a proposed collection of information to solicit comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

The Mineral Leasing Act (MLA) of 1920 (30 U.S.C. 181 *et seq.*) gives the Secretary of the Interior responsibility for oil and gas leasing on approximately 570 million acres of public lands and national forests, and private lands where mineral rights have been retained by the Federal Government. The Act of August 7, 1947, (Mineral Leasing Act of Acquired Lands) authorizes the Secretary to lease lands acquired by the United States (30 U.S.C. 341-359). The Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701 *et seq.*) establishes a public land policy and provides for the management, protection, development and enhancement of the public lands.

The regulations at 43 CFR Group 3150 establish procedures for conducting oil and gas geophysical exploration operations on public lands when authorization for such operations is required from the Bureau of Land Management (BLM). The regulations were last revised in 1988. The notice of intent (Form 3150-4) to conduct oil and gas geophysical exploration operations and the notice of completion (Form 3150-5) of oil and gas exploration operations were developed in 1990, and the information required from the public remains the same.

BLM needs the information requested on the notice of intent to allow it to process applications for geophysical exploration operations on public lands and manage environmental compliance requirements in accordance with the laws, regulations, and land use plans. BLM uses the information to determine that geophysical operation activities will be conducted in a manner consistent with the regulations, local land use plans, and Environmental

Assessments. BLM needs the information requested on the notice of completion to determine whether rehabilitation of the lands is satisfactory or whether additional rehabilitation is necessary.

The forms may be submitted in person or by mail to the proper BLM office. The company name, address and phone number is needed to identify the person/entity conducting operations. BLM assigns the BLM Case Number to track each specific operation. Where a particular operation requires State approval also, the State Case Number is assigned by the appropriate State agency so that the Bureau may coordinate exploration activity with the State. The legal land description is required to determine where the involved public lands are located.

Based on its experience administering onshore oil and gas geophysical exploration activities, BLM estimates the public reporting burden for completing the notice of intent (Form 3150-4) to conduct geophysical exploration operations is one hour. BLM estimates it will take an average time of 20 minutes to complete the notice of completion (Form 3150-5) of oil and gas exploration operations. The information required is clearly outlined on the form and in the terms and conditions attached. The information is already maintained by the respondents for their own record-keeping purposes and needs only to be transferred or attached to the forms.

It is estimated that approximately 600 notices of intent and 600 notices of completion will be filed annually for a total annual burden of 800 hours. Respondents vary from small businesses to major corporations.

Any interested member of the public may request and obtain, without charge, a copy of Form 3150-4 or 3150-5 by contacting the person identified under **FOR FURTHER INFORMATION CONTACT**. All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will also become part of the public record.

Dated: February 29, 1996.

Annetta L. Cheek,

*Regulatory Management Team, Chief.*

[FR Doc. 96-5104 Filed 3-4-96; 8:45 am]

BILLING CODE 4310-84-P

[WO-310-1310-01-24 1A]

**Extension of Currently Approved Information Collection; OMB Approval Number 1004-0145****AGENCY:** Bureau of Land Management, Interior.**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, the Bureau of Land Management (BLM) is announcing its intention to request extension of approval for the collection of information which will be used to determine the eligibility of an applicant to hold, explore for, and produce oil and gas on Federal lands. The information supplied allows the Bureau of Land Management to determine whether an applicant is qualified to conduct geophysical operations and to hold a lease to obtain a benefit under the terms of the Mineral Leasing Act of 1920.

**DATES:** Comments on the proposed information collection must be received by May 6, 1996 to be considered.

**ADDRESSES:** Comments may be mailed to: Regulatory Management Team (420), Bureau of Land Management, 1849 C Street NW, Room 401 LS Bldg., Washington, D.C. 20240.

Comments may be sent via Internet to: WO140@attmail.com. Please include "Attn: 1004-0145" and your name and address in your Internet message.

Comments may be hand delivered to the Bureau of Land Management Administrative record, Room 401 L Street, N.W., Washington, D.C.

Comments will be available for public review at the L Street address during regular business hours (7:45 a.m. to 4:15 p.m., Monday through Friday).

**FOR FURTHER INFORMATION CONTACT:** Gloria J. Austin, (202) 452-0340.

**SUPPLEMENTARY INFORMATION:** In accordance with 5 CFR 1320.8(d), BLM is required to provide a 60-day notice in the Federal Register concerning a proposed collection of information to solicit comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated,

electronic, mechanical, or other technological collection techniques or other forms of information technology.

The Mineral Leasing Act (MLA) of 1920 (30 U.S.C. 181 *et seq.*) gives the Secretary of the Interior responsibility for oil and gas leasing on approximately 570 million acres of public lands and national forests, and private lands where mineral rights have been reserved by the Federal Government. The Act of May 21, 1930 (30 U.S.C. 301-306), authorizes the leasing of oil and gas deposits under railroads and other rights-of-way. The Act of August 7, 1947 (Mineral Leasing Act of Acquired Lands), authorizes the Secretary to lease lands acquired by the United States (30 U.S.C. 341-359).

The regulations at 43 CFR Group 3100 outline procedures for members of the public to submit applications, offers, statements, petitions, and various forms. BLM needs the information requested in the applications, statements and petitions to determine whether an applicant is qualified to hold a lease to obtain a benefit under the terms of the MLA of 1920 and its subsequent amendments and implementing regulations.

BLM uses the information to determine the eligibility of an applicant to lease, explore for, and produce oil and gas on Federal lands. Applicants may submit information in person or by mail to the proper BLM office or the Department of the Interior, Minerals Management Service. Applicants are required to certify that they are citizens of the United States, and do not own or control in excess of 246,080 acres each in public domain and acquired lands of Federal oil and gas leases in a particular State as required by law under 30 U.S.C. 184(d)(1), and in accordance with the regulations at 43 CFR 3101.2 and 3102. Legal descriptions of lands are required to determine where the involved Federal lands are located. The names and addresses are needed to identify the applicant and allow the authorized officer to ensure that the applicant meets the requirements of the law. An attorney-in-fact or agent signature is needed only if an attorney or agent is filing the information required on behalf of an applicant or lessee. The information required on the statements, petitions, offers and applications is needed for orderly processing of oil and gas leases and is needed to comply with the terms and conditions of the statutes. BLM also needs the information to determine whether an entity is qualified to hold a lease to obtain a benefit. Attestations to compliance with the regulations concerning parties of interest and qualifications is necessary,

subject to criminal sanctions in accordance with 18 U.S.C., Section 1001. If the information contained on the applications statements, petitions and offers is not collected, the leasing of oil and gas could not occur to allow a benefit and millions of dollars in revenue to the Federal Government would be lost.

All information collections in the regulations at 43 CFR Subparts 3000-3120 that do not require a form are covered by this notice. BLM intends to submit these information collections collectively for approval by the Office of Management and Budget, as they were originally submitted and approved.

**BREAKDOWN OF INFORMATION COLLECTIONS AND TOTAL HOURS**

Information collection	No. of re-sponses	Report-ing hours per re-spond-ent	Total hours
3100.3-1 .....	30	1	30
3100.3-3 .....	50	1	50
3101.2-4(a) ...	10	1	10
3101.2-6 .....	10	1.5	15
3101.3-1 .....	50	1	50
3103.4-1 .....	20	2	40
3105.2 .....	150	2	300
3105.3 .....	50	2	100
3105.4 .....	20	1	20
3105.5 .....	50	1	50
3106.8-1 .....	40	1	40
3106.8-2 .....	60	1	60
3106.8-3 .....	100	2	200
3107.8 .....	30	1	30
3108.1 .....	150	.5	75
3108.2 .....	500	.5	250
3109.1 .....	20	1	20
3152.1 .....	20	1	20
3152.6 .....	20	1	20
3152.7 .....	20	1	20
Total ....	1,400	.....	1,400

Based on its experience managing oil and gas leasing activities, BLM estimates that it will take an average of 1 hour to complete the applications, petitions, offers and statements required. The applicants have access to records, plats and maps necessary for providing legal land descriptions. The type of information necessary is outlined in the regulations and is already maintained by the respondents for their own record-keeping purposes and needs only to be compiled in a reasonable format. The estimate also includes the time required for assembling the information, as well as the time of clerical personnel if needed.

BLM estimates that approximately 1,400 applications, offers, petitions or statements will be filed annually for a total of 1,400 reporting hours.

Respondents vary from individuals to small businesses and major corporations.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will also become part of the public record.

Dated February 29, 1996.

Annetta L. Cheek,

Chief, Regulatory Management Team.

[FR Doc. 96-5105 Filed 3-4-96; 8:45 am]

BILLING CODE 4310-84-P

[UT-040-06-1020-00]

### Notice of Intent to Amend Management Framework Plan

**AGENCY:** Bureau of Land Management, DOI.

**ACTION:** Notice of intent to amend Management Framework Plan.

**SUMMARY:** The Bureau of Land Management (BLM) is preparing an Environmental Assessment (EA) to consider a proposed amendment to the Pinyon Management Framework Plan (MFP). The proposed amendment would consider alternatives for additional opportunities for land tenure adjustments in Iron County.

**DATES:** The comment period for identification of issues for the proposed plan amendment will commence with the date of publication of this notice. Comments must be submitted on or before April 14, 1996.

**FOR FURTHER INFORMATION CONTACT:**

Arthur L. Tait, Beaver River Resource Area Manager, Bureau of Land Management, Cedar City District, 176 D.L. Sargent Drive, Cedar City, Utah 84720, telephone (801) 586-2401. Comments on the proposed plan amendment should be sent to the above address.

**SUPPLEMENTARY INFORMATION:** The Beaver River Resource Area (BRRA) Of the Cedar City district, BLM, is proposing to amend the Pinyon MFP to allow for land tenure adjustments on the following federal properties not previously identified in the MFP:

Federal land: 5,975.71 acres

Salt Lake Meridian

T. 35 S., R. 17 W.,  
Sec. 18 lots 1, 2, 3, 4; E $\frac{1}{2}$ SW $\frac{1}{4}$ ; E $\frac{1}{2}$ NW $\frac{1}{4}$ ;  
T. 35 S., R. 18 W.,  
Sections: 13; 14 E $\frac{1}{2}$ ; 24 NW $\frac{1}{4}$ ;  
T. 34 S., R. 17 W.,  
Sec. 19 lots 3 and 4 inclusive;  
T. 33 S., R. 17 W.,  
Sections: 23 W $\frac{1}{2}$ ; 34 W $\frac{1}{2}$ ; 35 W $\frac{1}{2}$ ;  
T. 31 S., R. 13 W.,  
Sections: 1 lots 4, 5, and 12; 3; 4 lots 1 to 4 and 7 to 10, inclusive; 5 lots 1 to 6,

inclusive, 11, and 12; 6 lots 1 and 2; 8 E $\frac{1}{2}$ ; 9; 10 W $\frac{1}{2}$ ; 20 E $\frac{1}{2}$ ;

The main purpose is to identify and analyze the land for exchange to private parties for acquisition of lands that result in a net gain of important and manageable resource values on public land. The United States is considering the acquisition of the following described *NON-FEDERAL*:

Land: 6,590.44 acres

Salt Lake Meridian

T. 35 S., R. 18 W.,  
Sections: 23 NW $\frac{1}{4}$ ; 25 W $\frac{1}{2}$ ; 27 N $\frac{1}{2}$ ; 29 N $\frac{1}{2}$ ; 33 S $\frac{1}{2}$ ; 34 N $\frac{1}{2}$ ; 35 W $\frac{1}{2}$ .  
T. 31 S., R. 15 W.,  
Sections: 2; 16; 36 W $\frac{1}{2}$ NE $\frac{1}{4}$ , W $\frac{1}{2}$ , and NW $\frac{1}{4}$ SE $\frac{1}{4}$ .  
T. 31 S., R. 17 W.,  
Section 32;  
T. 32 S., R. 17 W.,  
Sections: 2 lots 1 to 4, inclusive, S $\frac{1}{2}$ N $\frac{1}{2}$ , SW $\frac{1}{4}$ , N $\frac{1}{2}$ SE $\frac{1}{4}$ , and SW $\frac{1}{4}$ SE $\frac{1}{4}$ ; 16.  
T. 34 S., R. 19 W.,  
Section 16.

Lands transferred out of Federal Ownership as a result of the exchange, would be available to meet the various needs of the respective parties. An EA will be prepared to analyze the impacts of this proposed plan amendment and alternatives.

Public participation is being sought at this initial stage in the planning process to ensure the MFP amendment addresses all issues, problems and concerns from those interested in the management of lands within the BRRA. Necessary amendments to the approved plan will keep the document viable.

Doug Koza,

Acting State Director, Utah.

[FR Doc. 96-5020 Filed 3-4-96; 8:45 am]

BILLING CODE 4310-DQ-P

### Minerals Management Service

#### Aboriginal Title and Rights Claims Information in Cook Inlet and Prince William Sound, AL

**AGENCY:** Minerals Management Service (MMS), Department of the Interior.

**ACTION:** Request for information regarding claims of aboriginal title and rights in Cook Inlet and Prince William Sound of southern Alaska.

**SUMMARY:** This notice solicits factual data relevant to claims of aboriginal title and rights to unspecified portions of the Alaska Federal Outer Continental Shelf (OCS) included in the areas proposed for lease in OCS Lease Sales 149 (Cook Inlet) and 158 (Gulf of Alaska/Yakutat).

In a separate Federal Register notice, the Department of the Interior announced receipt of, and requested comments on, a petition for rulemaking on issues regarding claimed aboriginal title and aboriginal hunting and fishing rights of federally recognized tribes in Alaska exercisable on the OCS.

**DATES:** Comments on this request for information are requested through April 4, 1996.

**ADDRESSES:** Comments should be directed to: Paul Stang, Chief, Branch of Leasing Coordination, Office of Program Development and Coordination, (MS-4410) Minerals Management Service, 381 Elden Street, Herndon, Virginia 20270-4817. Please indicate that your comment is in response to the request for factual data regarding aboriginal title and rights on the Alaska OCS.

**FOR FURTHER INFORMATION CONTACT:**

William Quinn at (703) 787-1191.

**SUPPLEMENTARY INFORMATION:** The Minerals Management Service (MMS) exercises the delegated duties of the Secretary of the Interior under the Outer Continental Shelf (OCS) Lands Act, 43 U.S.C. 1331 *et seq.* for management of the resources of the OCS, the seabed seaward of three miles from the coastline (except in the case of Texas and Florida). Pursuant to the current 1992-1977 5-Year OCS Leasing Program, announced July 1, 1992, MMS has advanced to the final planning stages for the scheduled 1996 offering of natural gas and oil leases on the federal OCS in Cook Inlet, Sale 149. This is the fourth federal OCS lease sale in Cook Inlet. The State of Alaska has included portions of Cook Inlet in 28 of its offshore lease sales.

The Native Villages of Eyak, Tatilek, Chenega, Port Graham, and Nanwalek have, through correspondence, petition and litigation, advised MMS of their claims of aboriginal title and aboriginal hunting and fishing rights to unspecified portions of the sale area. The Villages are located in the Cook Inlet and Prince William Sound area of southern Alaska. The Villages have submitted a petition for rulemaking requesting the promulgation of regulations that recognize and protect such Villages' "exclusive fishing rights" on the Alaska OCS. Petitioners claim that there is legal support for the existence and recognition of such rights under the doctrine of aboriginal title and that such Villages have "exclusively used and occupied" the OCS for "subsistence purposes" since "time immemorial". The Villages assert that Sale 149 would interfere with the existence of their rights and deprive them of mineral income rightfully theirs. This information will also be considered in making final decisions on Sale 149, Cook Inlet and Sale 158, Gulf of Alaska, Yakutat.

The Government has consistently taken the position that no person or entity has title to, or hunting and fishing rights on, the Alaska OCS, which is

subject to the paramount authority of the Federal Government exercised pursuant to the above cited statute. In fairness to the Villages, however, the MMS is carefully pursuing a factual inquiry into the potential nature and extent of such Native claims. MMS requests that any knowledgeable party submit any information pertinent to the Villages' claims regarding the federal OCS, whether such information supports or disputes the claims.

The MMS has received a report on claimed aboriginal use of the OCS from Kayak Island to the Lower Cook Inlet. That report suggests that even if aboriginal claims could exist on the OCS, the factual predicate for a claim by the Native Villages of Eyak, Tatilek, Chenega, Port Graham, and Nanwalek, is not present. The MMS invites comments on that report which can be obtained by contacting Paul Stag or William Quinn at the addresses shown above.

MMS also invites knowledgeable parties to provide factual responses to any of the following questions and to supply any other relevant information:

1. What is the physical/territorial location of the "ancestral fishing areas" on the federal OCS of each of the five Native Villages? Please cite known anthropological data regarding historical use indicating that the use occurred more than three miles from the coastline on the federal OCS.

2. What is the size of each Village's historical fishing areas on the federal OCS? Do any of them overlap? Have the dimensions and geographic descriptions of such areas remained constant over time? If not, please describe how they have changed.

3. How long has each Village used such areas on the federal OCS? During this period has such historical use been continuous and exclusive of others?

4. For what type of subsistence uses have such areas on the federal OCS been historically used?

a. To what extent, if any, have they been exclusively and continually used in this manner? If so for how long? What distance from the coast have these activities occurred?

b. If such use was ever interrupted, for what reason and for how long?

c. What species of fish, invertebrates, birds, and/or marine mammals were hunted over the federal OCS?

(i) During what time of year was each species hunted?

(ii) At what depth?

(iii) What kinds of equipment were historically used to harvest such resources? Are newer or different methods and equipment used now? If so, when did such changes occur?

5. What was the impact of Russian or American expansion into the region on such uses?

6. Has the possession and use of such areas been exclusive of other Alaska Native entities?

If not, is there any evidence of "joint" or "concurrent" use by other Villages? If so, what is the basis and nature of such joint usage and when did such usage begin?

7. When was the first use of the seabed and its resources and by whom? Its mineral resources (including geological and geophysical work preparatory to such exploitation)?

MMS will consider all such information (along with responses to the other request mentioned above) in making final decisions on Sale 149 and Sale 158.

Dated: February 26, 1996.  
Cynthia Quarterman,  
*Director, Minerals Management Service.*  
[FR Doc. 96-5008 Filed 3-4-96; 8:45 am]  
BILLING CODE 4310-MR-M

## Bureau of Mines

### Termination of Advisory Committee

**AGENCY:** Bureau of Mines, Interior.  
**ACTION:** Notice of termination of the U.S. Bureau of Mines Advisory Board.

**SUMMARY:** In accordance with 41 CFR 101-6.1027, Termination of advisory committees, the U.S. Bureau of Mines Advisory Board terminates its charter, effective November 7, 1995.

**DATES:** Termination of the charter of the U.S. Bureau of Mines Advisory Board, will be effective as of November 7, 1995.

**ADDRESSES:** U.S. Bureau of Mines, U.S. Department of the Interior, 810 Seventh Street, N.W., Washington, D.C. 20241. Tel: (202) 501-9365.

**FOR FURTHER INFORMATION CONTACT:** For information contact David S. Brown at the address and telephone identified above.

Dated: January 26, 1996.  
Bonnie R. Cohen,  
*Assistant Secretary—Policy, Management and Budget.*  
[FR Doc. 96-5000 Filed 3-4-96; 8:45 am]  
BILLING CODE 4310-53-M

## National Park Service

### National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received

by the National Park Service before February 24, 1996. Pursuant to section 60.13 of 36 CFR Part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, P.O. Box 37127, Washington, D.C. 20013-7127. Written comments should be submitted by March 20, 1996.

Carol D. Shull,  
*Keeper of the National Register.*

## FLORIDA

### Volusia County

Bethune—Cookman College Historic District, (Historic Resources of Daytona Beach), 620 Dr. Mary McLeod Bethune Blvd., Daytona Beach, 96000298

## MARYLAND

### Frederick County

Bowlus Mill House, 8123 Old Hagerstown Rd., Spoolsville, 96000300

### Somerset County

Tull, William T., House, MD 413, W side of, Westover, 96000302

### Worcester County

Crockett House, 900 Market St., Pocomoke City, 96000299

Mar-Va Theater, 103 Market St., Pocomoke City, 96000301

## MASSACHUSETTS

### Worcester County

Whitney Tavern, 11 Patriots Rd., Templeton and Gardner, 96000304

## NEW YORK

### Erie County

Citizens National Bank, 5 W. Main St., Springville, 96000295

Scobey Power Plant and Dam, Jct. of Scobey Hill Rd. and Cattaraugus Cr., Springville vicinity, 96000296

## OKLAHOMA

### Garfield County

Enid Cemetery and Calvary Catholic Cemetery, 200 block of W. Willow Ave., Enid, 96000305

## WISCONSIN

### Door County

Meridian (schooner) (Great Lakes Shipwrecks of Wisconsin) Address Restricted, Sister Bay vicinity, 96000294

### La Crosse County

District School No. 1, US 14/61 E of Jct. with WI 35, Shelby, 96000303

[FR Doc. 96-5026 Filed 3-4-96; 8:45 am]

BILLING CODE 4310-70-P +.



**Bureau of Reclamation****Bay-Delta Advisory Council Meeting**

**AGENCY:** Bureau of Reclamation, Interior.

**ACTION:** Notice of meeting.

**SUMMARY:** The Bay-Delta Advisory Council (BDAC) will meet to discuss several issues including: review and status of the CALFED Bay-Delta Program; financial strategy for the long-term program; review and discussion of the draft alternatives; and scoping for the long-term program. This meeting is open to the public. For the meeting, interested persons may make oral statements to the BDAC or may file written statements for consideration.

**DATES:** The Bay-Delta Advisory Council meeting will be held from 9:00 am to 4:00 pm on Thursday, March 21, 1996.

**ADDRESS:** The Bay-Delta Advisory Council will meet at the Beverly Garland Hotel, 1780 Tribute Road (at Exposition Boulevard/West), Sacramento, CA.

**CONTACT PERSON FOR MORE INFORMATION:**

Sharon Gross, CALFED Bay-Delta Program, at (916) 657-2666. If reasonable accommodation is needed due to a disability, please contact the Equal Employment Opportunity Office at (916) 653-6952 or TDD (916) 653-6934 at least one week prior to the meeting.

**SUPPLEMENTARY INFORMATION:** The San Francisco Bay/Sacramento-San Joaquin Delta Estuary (Bay-Delta system) is a critically important part of California's natural environment and economy. In recognition of the serious problems facing the region and the complex resource management decisions that must be made, the state of California and the Federal government are working together to stabilize, protect, restore, and enhance the Bay-Delta system. The State and Federal agencies with management and regulatory responsibilities in the Bay-Delta system are working together as CALFED to provide policy direction and oversight for the process.

One area of Bay-Delta management includes the establishment of a joint State-Federal process to develop long-term solutions to problems in the Bay-Delta system related to fish and wildlife, water supply reliability, natural disasters, and water quality. The intent is to develop a comprehensive and balanced plan which addresses all of the resource problems. This effort is being carried out under the policy direction of CALFED. A group of citizen advisors representing California's agricultural,

environmental, urban, business, fishing, and other interests who have a stake in finding long term solutions for the problems affecting the Bay-Delta system has been chartered under the Federal Advisory Committee Act (FACA) as the Bay-Delta Advisory Council (BDAC) to advise CALFED on the program mission, problems to be addressed, and objectives for the CALFED Bay-Delta Program. BDAC provides a forum to help ensure public participation, and will review reports and other materials prepared by CALFED staff.

Minutes of the meeting will be maintained by the CALFED Bay-Delta Program, Suite 1155, 1416 Ninth Street, Sacramento, CA 95814, and will be available for public inspection during regular business hours, Monday through Friday within 30 days following the meeting.

Dated: February 27, 1996.  
Roger Patterson,  
*Regional Director, Mid-Pacific Region.*  
[FR Doc. 96-5098 Filed 3-4-96; 8:45 am]  
BILLING CODE 4310-94-M

**Office of Surface Mining Reclamation and Enforcement****Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act**

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. 35). Copies of the proposed collection of information and related form may be obtained by contacting the Bureau's clearance officer at the phone number listed below. Comments and suggestions on the proposal should be made directly to the Bureau clearance officer and to the Office of Management and Budget, Paperwork Reduction Project, Washington, DC 20503, telephone 202-395-7340.

**Title:** AVS Industry Seminar Questionnaire.

**OMB Approval Number:** Not yet assigned.

**Abstract:** Executive Order 12862 requires agencies to survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services. The information supplied by this questionnaire will determine customer satisfaction with AVS Industry Seminars and to identify future topics of interest.

**Bureau form number:** None.

**Frequency:** On Occasion.  
**Description of Respondents:** Industry groups.

**Estimated Completion Time:** 10 minutes.

**Annual Responses:** 75.

**Annual Burden Hours:** 15.

**Bureau Clearance Officer:** John A. Trelease, 202-208-2617.

Dated: February 23, 1996.

Gene E. Krueger,  
*Acting Chief, Office of Technology Development and Transfer.*

[FR Doc. 96-5108 Filed 3-4-96; 8:45 am]

BILLING CODE 4310-05-M

**DEPARTMENT OF JUSTICE****Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response Compensation and Liability Act of 1980, as Amended**

Notice is hereby given that a proposed consent decree in the consolidated actions entitled *Elf Atochem North America, Inc. versus United States, et al.*, Civil Action No. 92-7458 and *United States versus Witco Corporation*, Civil Action No. 94-0662 (E.D. Pa.), was lodged on February 27, 1996, with the United States District Court for the Eastern District of Pennsylvania. The consent decree resolves the United States' claim, on behalf of the U.S. Environmental Protection Agency ("EPA"), against defendant Witco Corporation ("Witco") in Civil Action No. 94-0662, and Witco's counterclaim against the United States, on behalf of the Departments of Commerce, the Army, and the General Services Administration ("Settling Federal Agencies"), in Civil Action No. 94-0662 under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA") for contamination at the Myers Property Superfund Site in Franklin Township, Hunterdon County, New Jersey (the "Site"). In the proposed consent decree, Witco will pay the United States \$400,000 in settlement of the United States' claims for past response costs incurred by EPA at the Site, and to dismiss its counterclaim against the Settling Federal Agencies. The Settling Federal Agencies agree to pay into the Hazardous Substance Superfund the sum of \$600,000 in reimbursement of EPA's past response costs.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the proposed



consent decree. Comments should be addressed to the Assistant Attorney General for the Environment and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to *Elf Atochem North America, Inc. versus United States, et al.*, Civil Action No. 92-7458 and *United States versus Witco Corporation*, Civil Action No. 94-0662 (E.D. Pa.), DOJ Ref. Number 90-11-2-662A.

The proposed consent decree may be examined at the Office of the United States Attorney, 615 Chestnut Street, Suite 1250, Philadelphia, Pennsylvania 19106; the Region II Office of the Environmental Protection Agency, 290 Broadway, New York, NY 10278; and the Consent Decree Library, 1120 G Street, NW., 4th Floor, Washington, DC 20005, (202) 624-0892. A copy of the proposed consent decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, NW., 4th floor, Washington, DC 20005. In requesting a copy, please refer to the referenced case and enclose a check in the amount of \$7.50 (25 cents per page reproduction costs), payable to the Consent Decree Library.

Joel M. Gross,

Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 96-5034 Filed 3-4-96; 8:45 am]

BILLING CODE 4410-01-M

#### **Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act of 1980**

In accordance with Departmental policy, 28 CFR 50.7, and 42 U.S.C. 9622(d)(2), notice is hereby given that on February 20, 1996, a Consent Decree was lodged in *United States v. Hercules, et al.*, Civil Action No. 89-562-SLR, with the United States District Court for the District of Delaware.

The Complaint in this case, as amended, was filed under Sections 106 and 107 of the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended ("CERCLA"), 42 U.S.C. §§ 9606 and 9607, with respect to the Delaware Sand & Gravel Superfund Site ("DS&G Site") located in New Castle County, Delaware, against numerous defendants, many of whom have agreed to settlement terms under prior consent decrees. Pursuant to the terms of the Consent Decree with Harvey & Harvey, Inc., the United States will receive a payment of \$1.3 million over four years for costs incurred in connection with the Site.

The Department of Justice will receive comments relating to the proposed Consent Decree for a period of thirty days from the date of publication of this notice. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to *United States v. Hercules, et al.*, Civil Action No. 89-562-SLR, Ref. No. 90-11-2-298. The proposed Consent Decree may be examined at the office of the United States Attorney, District of Delaware, Chemical Bank Plaza, 1201 Market Street, Suite 100, Wilmington, Delaware 19899. Copies of the Consent Decree may also be examined and obtained by mail at the Consent Decree Library, 1120 G Street, NW., 4th Floor, Washington, DC 20005 (202-624-0892) and the offices of the Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107. When requesting a copy by mail, please enclose a check in the amount of \$11.00 (twenty-five cents per page reproduction costs) payable to the "Consent Decree Library."

Joel M. Gross,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 96-5035 Filed 3-4-96; 8:45 am]

BILLING CODE 4410-01-M

#### **Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act**

In accordance with Departmental policy and 28 CFR § 50.7, notice is hereby given that on February 21, 1996, a proposed consent decree in *United States v. Reliance Battery Mfg. Co.*, Civil Action No. 1-94-CV-80018, was lodged with the United States District Court for the Southern District of Iowa. This consent decree represents a settlement of claims against Reliance Battery Mfg. Co., William S. Grant, and Rosemary V. Grant ("Defendants") under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), 42 U.S.C. § 9601 *et seq.*

On April 25, 1994, the United States filed a Complaint pursuant to Sections 107(a) and (c)(3) of the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), 42 U.S.C. § 9607(a) and (c)(3) for response costs and punitive damages against Defendants. Subsequently, the United States and Defendants reached a settlement which resolves the issues set forth in the Complaint. Under this settlement

between the United States and Defendants, Defendants will pay the United States \$20,000 towards response costs incurred by the United States in connection with the release of hazardous substances from the Reliance Battery Mfg. Co. facility in Council Bluffs, Iowa. The consent decree also provides that Defendants will clean up existing contamination at the Reliance Battery Mfg. Co. site and will reimburse the United States for all costs it incurs in connection with this cleanup. In addition, the consent decree contains measures designed to prevent future releases of hazardous substances to the environment.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to *United States v. Reliance Battery Mfg. Co.*, D.J. ref. 90-11-2-961.

The proposed consent decree may be examined at the following locations: (1) Office of the United States Attorney, Southern District of Iowa, 115 U.S. Courthouse, East 1st and Walnut Streets, Des Moines, Iowa; (2) Office of the Environmental Protection Agency, Region VII, 726 Minnesota Ave, Kansas City, Kansas; and (3) the Consent Decree Library, 1120 G Street, NW., 4th Floor, Washington, DC 20005. A copy of the proposed consent decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, NW., 4th Floor, Washington, DC 20005. In requesting a copy, please enclose a check in the amount of \$13.00 (25 cents per page reproduction costs) payable to the Consent Decree Library.

Joel M. Gross,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 96-5036 Filed 3-4-96; 8:45 am]

BILLING CODE 4410-01-M

#### **Antitrust Division**

##### **United States v. Browning-Ferris, Inc.; Proposed Final Judgment and Competitive Impact Statement**

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16 (b)-(h), that a proposed Final Consent Judgment, Stipulation, and Competitive Impact Statement have been filed with the United States District Court for the District of Columbia in the above-captioned case.

On February 15, 1996, the United States filed a civil antitrust Complaint to prevent and restrain Browning-Ferris Industries, Inc. ("BFI"), Browning-Ferris Industries of Iowa, Inc. ("BFII"), and Browning-Ferris Industries of Tennessee, Inc. ("BFIT") from maintaining and enhancing their market power by using contracts that have restrictive and anticompetitive effects, in violation of Section 2 of the Sherman Act, 156 U.S.C. 2.

The Complaint alleges that: (1) Defendant BFIT has market power in small containerized hauling service in the Memphis, TN market and Defendant BFII has market power in small containerized hauling service in the Dubuque, IA market; (2) Defendants, acting with specific intent, used and enforced contracts containing restrictive provisions to exclude and constrain competition and to maintain and enhance their market power in small containerized hauling service in those markets; (3) in the context of their large market shares and market power, and Dubuque markets has had anticompetitive and exclusionary effects by significantly increasing barriers to entry facing new entrants and barriers to expansion faced by small incumbents; (4) Defendants' market power is maintained and enhanced by their use and enforcement of those contracts; and, (5) as a result, there is a dangerous probability that Defendants will achieve monopoly power in the Memphis and Dubuque markets.

The proposed Final Judgment would require that in dealing with small-container customers in the Memphis and Dubuque markets, Defendants only enter into contract containing significantly less restrictive terms than the contracts they now use in those markets. Specifically, the Defendants will be prohibited from using any contract with small-container customers in the Memphis and Dubuque markets that:

(1) Has an initial term longer than two years (unless a longer term is requested by the customer and other conditions are met);

(2) Has any renewal term longer than one year;

(3) Requires the customer give notice of termination more than 30 days prior to the end of a term;

(4) Requires the customer to pay liquidated damages over 3 times the greater of its prior monthly charge or its average monthly charge during the first year of the initial term of the customer's contract, or over 2 times the greater of its prior monthly charge or its average monthly charge thereafter;

(5) Is not labeled "Contract for Solid Waste Services" and is not easily readable; or

(6) Requires a customer to give BFI the right or opportunity to provide hauling services for all solid wastes and recyclables, unless the customer affirmatively indicates that is its desire.

The proposed Consent Final Judgment also requires that the Defendants notify customers in the two relevant markets of these changes and prohibits the Defendants from enforcing terms in existing contracts that are inconsistent with the settlement in those markets. Furthermore, Defendants would be prohibited from enforcing provisions in existing contracts that are inconsistent with the Final Judgment.

Public comment is invited within the statutory 60-day period. Such comments will be published in the Federal Register and filed with the Court. Comments should be addressed to Anthony V. Nanni, Chief, Litigation I Section, U.S. Department of Justice, Antitrust Division, 1401 H St., NW., Suite 4000, Washington, DC 20530. (phone 202/307-6576).

Rebecca P. Dick,

*Deputy Director of Operations.*

United States District Court for the District of Columbia

In the matter of *United States of America, Plaintiff, v. Browning-Ferris Industries of Iowa, Inc., Browning-Ferris Industries of Tennessee, Inc., and Browning-Ferris Industries, Inc.*, Defendants.

[Civil Action No.: 1-96-V00297]

Filed: February 15, 1996.

#### Stipulation

It is stipulated by and between the undersigned parties, by their respective attorneys, that:

1. The Court has jurisdiction over the subject matter of this action and over each of the parties hereto for the purposes of this proceeding. Defendant Browning-Ferris Industries, Inc. transacts business and is found within the district. Defendants Browning-Ferris Industries of Tennessee, Inc. and Browning-Ferris Industries of Iowa, Inc. consent to personal jurisdiction in this proceeding. Defendants waive any objections as to venue and stipulate that venue for this action is proper in the District of Columbia;

2. The parties consent that a Final Judgment in the form hereto attached may be filed and entered by the Court, upon the motion of any party or upon the Court's own motion, at any time after compliance with the requirements of the Antitrust Procedures and Penalties Act (15 U.S.C. 16 (b)-(h)), and without further notice to any party or

other proceedings, provided that Plaintiff has not withdrawn its consent, which it may do at any time before the entry of the proposed Final Judgment by serving notice thereof on the Defendants and by filing that notice with the Court; and

3. Defendants agree to be bound by the provisions of the proposed Final Judgment pending its approval by the Court. If the Plaintiff withdraws its consent or if the proposed Final Judgment is not entered pursuant to this Stipulation, this Stipulation shall be of no effect whatsoever, and the making of this Stipulation shall be without prejudice to any party in this or in any other proceeding.

Dated this 15th day of February, 1996.

Respectfully submitted,

For the plaintiff the United States of America:

Anne K. Bingham,

*Assistant Attorney General, Antitrust Division, U.S. Department of Justice.*

Lawrence R. Fullerton,

*Deputy Assistant Attorney General.*

Rebecca P. Dick,

*Deputy Director of Operations.*

Anthony V. Nanni,

*Chief, Litigation I Section.*

Willie L. Hudgins, Jr.,

*DC Bar #37127.*

Nancy H. McMillen.

Peter H. Goldberg,

*DC Bar #055608.*

Evangelina Almirantearena,

*Attorneys, U.S. Department of Justice, Antitrust Division, City Center Building, Suite 4000, 1401 H Street, NW., Washington, DC 20530, 202/307-5777.*

For Defendants Browning-Ferris Industries of Iowa, Inc., Browning-Ferris Industries of Tennessee, Inc., and Browning-Ferris Industries, Inc.:

David Foster,

*Esquire, DC Bar #358247, Fulbright & Jaworski L.L.P., 801 Pennsylvania Ave., NW, Market Square, Washington, DC 20004-2604, 202/662-0200.*

Richard N. Carrell,

*Esquire, Fulbright & Jaworski L.L.P., 1301 McKinney, Suite 5100, Houston, Texas 77010-3095, 713/651-5151.*

Rufus Wallingford,

*Esquire, Senior Vice President & General Counsel, Browning-Ferris Industries, Inc., 757 N. Eldridge at Memorial Drive, Houston, Texas 77079, 713/870-8100.*

Lee J. Keller,

*Esquire, Senior Attorney, Browning-Ferris Industries, Inc., 757 N. Eldridge at Memorial Drive, Houston, Texas 77079, 713/870-8100.*

Attorneys for Defendants.

United States District Court for the District of Columbia

In the matter of *United States of America*, Plaintiff, v. *Browning-Ferris Industries of Iowa, Inc.*, *Browning-Ferris Industries of Tennessee, Inc.*, and *Browning-Ferris Industries, Inc.*, Defendants.

[Civil Action No.: 1-96-V00297]

Filed: Feb. 15, 1996.

Final Judgment

Whereas Plaintiff, United States of America, having filed its Complaint in this action on February 15, 1996, and Plaintiff and Defendants, by their respective attorneys, having consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law; and without this Final Judgment constituting any evidence or admission by any party with respect to any issue of fact or law;

Now, therefore, before any testimony is taken, and without trial or adjudication of any issue of fact or law, and upon consent of the parties, it is hereby

Ordered, adjudged and decreed as follows:

I. Jurisdiction

This Court has jurisdiction of the subject matter of this action and of the persons of the Defendants, Browning-Ferris Industries, Inc., Browning-Ferris Industries of Tennessee, Inc., and Browning-Ferris Industries of Iowa, Inc. The Complaint states a claim upon which relief may be granted against the Defendants under Section 2 of the Sherman Act, 15 U.S.C. 2.

II. Definitions

As used in this Final Judgment:

(A) "Memphis market" means the counties of Shelby, TN; Fayette, TN; Crittenden, AK; DeSoto, MS; Marshall, MS; Tate, MS; and Tunica, MS.

(B) "Dubuque market" means the counties of Dubuque and Jackson, IA.

(C) "Solid waste hauling" means the collection and transportation to a disposal site of trash and garbage (but not construction and demolition debris; medical waste; hazardous waste; organic waste; or special waste, such as contaminated soil, or sludge; or recyclable materials) from residential, commercial and industrial customers. Solid waste hauling includes hand pick-up, containerized pick-up, and roll-off service.

(D) "Defendants" means defendant Browning-Ferris Industries, Inc., a Delaware corporation with its headquarters in Houston, Texas, defendant Browning-Ferris Industries of Tennessee, Inc., a Tennessee corporation with offices in Memphis,

TN, and defendant Browning-Ferris Industries of Iowa, Inc., an Iowa corporation with offices in Des Moines, IA, and includes their officers, directors, managers, agents, employees, successors, assigns, parents and subsidiaries.

(E) "Small Container" means a 1 to 10 cubic yard container.

(F) "Small Containerized Solid Waste Hauling Service" means providing solid waste hauling service to customers by providing the customer with a Small Container that is picked up mechanically using a frontload, rearload, or sideload truck, and expressly excludes hand pick-up service, and service using stationary compactors.

(G) "Customer" means a Small Containerized Solid Waste Hauling Service customer.

III. Applicability

This Final Judgment applies to Defendants and to their officers, directors, managers, agents, and employees, successors, assigns, parents and subsidiaries, and to all other persons in active concert or participation with any of them who shall have received actual notice of this Final Judgment by personal service or otherwise. Nothing contained in this Final Judgment is or has been created for the benefit of any third party, and nothing herein shall be construed to provide any rights to any third party.

IV. Prohibited Conduct

Defendants are enjoined and restrained as follows:

(A) Except as set forth in paragraph IV (B) and (G), Defendants shall not enter into any contract with a Customer for a service location in the Memphis or Dubuque markets that:

(1) Has an initial term longer than two (2) years;

(2) Has any renewal term longer than one (1) year;

(3) Requires that the Customer give Defendants notice of termination more than thirty (3) days prior to the end of any initial term or renewal term;

(4) Requires that the Customer pay liquidated damages in excess of three times the greater of its prior monthly charge or its average monthly charge over the most recent six months during the first year it is a Customer of Defendants;

(5) Requires that the Customer pay liquidated damages in excess of two times the greater of its prior monthly charge or its average monthly charge over the most recent six months after the Customer has been a Customer of

Defendants for a continuous period in excess of one (1) year;

(6) Is not easily readable (e.g., formatting and type-face) and is not labeled, in large letters, CONTRACT FOR SOLID WASTE SERVICES; or

(7) Requires a Customer to give Defendants the right or opportunity to provide hauling service for recyclable or more than one type of solid waste hauling service for a Customer unless the Customer affirmatively indicates its desire for all such services on the front of the contract.

(B) Notwithstanding the provisions of paragraph IV(A) of this Final Judgment. Defendants may enter into a contract with a Customer for a service location in the Memphis or Dubuque markets with an initial term in excess of two years provided that:

(1) Defendants have not implemented any organized, management—authorized sales or marketing plan designed, through pricing or other incentives, to induce Customers to use other than the form contracts Defendants are required herein to offer generally to Customers;

(2) The Customer has the right to terminate the contract after 2 years by giving notice to Defendants thirty (30) days or more prior to the end of that 2 year period; and,

(3) The contract otherwise complies with the provisions of paragraph IV(A)(2)–(7).

(C) From the date of filing of an executed Stipulation in the form attached hereto as Exhibit A, Defendants shall offer to new Customers with service locations in the Memphis and Dubuque markets only contracts that conform to the requirements of paragraphs IV(A) or (B) of this Final Judgment, except as provided in IV(G).

(D) Except as provided in IV(G), Defendants shall send to all existing Customers with service locations in the Memphis and Dubuque markets with contracts having an initial term longer than 2 years and which otherwise do not conform with paragraph IV(B) a notice in the form attached hereto as Exhibit B (for Memphis customers) and as Exhibit C (for Dubuque customers) in accordance with the following schedule:

(1) Defendants shall send notices to Customers with service locations in the Memphis market within ninety (90) days following entry of this Final Judgment; and

(2) Defendants shall send notices to Customers with service locations in the Dubuque market within thirty (30) days following the entry of this Final Judgment.

(E) Except as provided in IV(G), for each Customer with a contract having

an initial term longer than 2 years and which otherwise does not conform to paragraph IV(B) that enters a renewal term 120 days after entry of this Final Judgment, Defendants shall send a reminder to that Customer in the form attached hereto as Exhibit D ninety (90) days or more prior to the effective date of the renewal term. This reminder may be sent to the customer as part of a monthly bill, but if it is, it must be displayed on a separate page and in large print.

(F) Upon entry of this Final Judgment, Defendants may enforce existing contract provisions only to an extent consistent with this Final Judgment. (For example, if an existing service agreement provides for six months' liquidated damages, Defendants may only seek three months' worth of such damages, consistent with IV(A)(4)).

(G) Notwithstanding the provisions of this Final Judgment, Defendants may enter into contracts with municipal or governmental entities that are not in compliance with paragraphs IV(A)–(F) provided that those contracts are awarded to Defendants on the basis of a formal request for bids or a formal request for proposals issued by the Customer.

(H) Notwithstanding the provisions of this Final Judgment, Defendants shall not be required to do business with any Customer.

#### V. Reporting

(A) To determine or secure compliance with this Final Judgment, duly authorized representatives of the Plaintiff shall, upon written request of the Assistant Attorney General in charge of the Antitrust Division, on reasonable notice given to Defendants at this principal offices, subject to any lawful privilege, be promised:

(1) Access during normal office hours to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other documents and records in the possession, custody, or control of Defendants, which may have counsel present, relating to any matters contained in this Final Judgment.

(2) Subject to the reasonable convenience of Defendants and without restraint or interference from them, to interview officers, employees, or agents of Defendants, who may have counsel present, regarding any matters contained in this Final Judgment.

(B) Upon written request of the Assistant Attorney General in charge of the Antitrust Division, on reasonable notice given to Defendants at this principal offices, subject to any lawful privilege, Defendants shall submit such written reports, under oath if requested, with respect to any matters contained in this Final Judgment.

(C) No information or documents obtained by the means provided by this Section shall be divulged by the Plaintiff to any person other than a duly authorized representative of the Executive Branch of the United States government, except in the course of legal proceedings to which the United States is a party, or for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

(D) If at the time information or documents are furnished by Defendants to Plaintiff, Defendants represent and identify in writing the material in any such information or document to which a claim or protection may be asserted under Rule 26(c)(7) of the Federal Rules of Civil Procedure, and Defendants mark each pertinent page of such material "Subject to claim of protection under Rule 26(c)(7) of the Federal Rules of Civil Procedure," then ten days notice shall be given by Plaintiff to Defendants prior to divulging such material in any legal proceeding (other than a grand jury proceeding) to which Defendants are not a party.

#### VI. Further Elements of Judgment

(A) This Final Judgment shall expire on the tenth anniversary of the date of its entry.

(B) Jurisdiction is retained by this Court over this action and the parties thereto for the purpose of enabling any of the parties thereto to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify or terminate any of its provision, to enforce compliance, and to punish violations of its provisions.

#### VII. Public Interest

Entry of this Final Judgment is in the public interest.

Entered: \_\_\_\_\_

UNITED STATES DISTRICT JUDGE

#### EXHIBIT A

United States District Court for the District of Columbia

*United States of America*, Plaintiff, v.  
*Browning-Ferris Industries of Iowa, Inc.*,  
*Browning-Ferris Industries of Tennessee, Inc.*,  
and *Browning-Ferris Industries, Inc.*,  
Defendants.

[Civil Action No.: 1–96–V00297]

Filed: February 15, 1996.

#### Stipulation

It is stipulated by and between the undersigned parties, by their respective attorneys, that:

1. The Court has jurisdiction over the subject matter of this action and over each of the parties hereto for the purposes of this proceeding. Defendant Browning-Ferris Industries, Inc. transacts business and is found within the district. Defendants Browning-Ferris Industries of Tennessee, Inc. and Browning-Ferris Industries of Iowa, Inc. consent to personal jurisdiction in this proceeding. Defendants waive any objections as to venue and stipulate that venue for this action is proper in the District of Columbia;

2. The parties consent that a Final Judgment in the form hereto attached may be filed and entered by the Court, upon the motion of any party or upon the Court's own motion, at any time after compliance with the requirements of the Antitrust Procedures and Penalties Act (15 U.S.C. § 16 (b)–(h)), and without further notice to any party or other proceedings, provided that Plaintiff has not withdrawn its consent, which it may do at any time before the entry of the proposed Final Judgment by serving notice thereof on the Defendants and by filing that notice with the Court; and

3. Defendants agree to be bound by the provisions of the proposed Final Judgment pending its approval by the Court. If the Plaintiff withdraws its consent or if the proposed Final Judgment is not entered pursuant to this Stipulation, this Stipulation shall be of no effect whatsoever, and the making of this Stipulation shall be without prejudice to any party in this or in any other proceeding.

Dated this \_\_\_\_\_th day of \_\_\_\_\_, 1996.  
Respectfully submitted,

For the Plaintiff the United States of America.

Anne K. Bingaman,  
Assistant Attorney General, Antitrust  
Division, U.S. Department of Justice.  
Lawrence R. Fullerton,  
Deputy Assistant Attorney General.  
Rebecca P. Dick,  
Deputy Director of Operations.  
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20530, 202/307-5777.

For defendants Browning-Ferris Industries  
of Iowa, Inc., Browning-Ferris Industries of  
Tennessee, Inc., and Browning-Ferris  
Industries, Inc.:

David Foster, Esquire,  
DC Bar #358247, Fulbright & Jaworski, 801  
Pennsylvania Ave., NW., Market Square,  
Washington, D.C. 20004-2604, 202/662-0200.

## EXHIBIT B

### Notice to Customers

Dear Customer:

BFI is offering a new two year contract to  
its small containerized solid waste hauling  
customers with service locations in [insert  
market here]. In most cases, this new contract  
will have terms that are more advantageous  
to customers than their current contracts.  
This new contract has the following features:

- an initial term of no longer than 2 years  
(unless you request a longer term);
- a renewal term of 1 year;
- at the end of your initial term, you may  
take no action and your contract will renew  
or you may choose not to renew by giving us  
notice at any time up to 30 days prior to the  
end of the initial term;
- if you request a contract with a term  
longer than 2 years, you can cancel that  
contract by giving us notice at any time up  
to 30 days prior to the end of the first 2 years;
- you can choose to terminate the contract  
at any other time, but you will be required  
to pay, as liquidated damages, no more than  
3 times the greater of your prior monthly or  
average monthly charge, but if you have been  
a customer continuously for more than 1  
year, the liquidated damages would be  
reduced to 2 times the greater of your prior  
monthly or average monthly charge;
- you will be able to choose on the  
contract which specific types of waste  
hauling services you would like us to  
perform.

On or before the termination date of your  
existing service contract, BFI will offer you  
continued service under the new contract.  
BUT AS AN EXISTING CUSTOMER, YOU  
WILL IMMEDIATELY GAIN THE  
ADVANTAGES OF THE REVISED

CONTRACT SINCE BFI WILL NOT  
ENFORCE ANY PROVISION IN YOUR  
CONTRACT IN ANY MANNER  
INCONSISTENT WITH ONE OF THE NEW  
TERMS OFFERED ABOVE. THERE IS,  
THEREFORE, NO NEED TO SIGN A  
REVISED CONTRACT AT THIS TIME.  
HOWEVER, IF YOU WOULD LIKE TO  
ENTER A NEW CONTRACT IN THE  
MEANTIME, PLEASE SEND A LETTER TO  
[insert name and address] AND WE WILL  
CONTACT YOU.

Thank you for your attention.

## EXHIBIT C

### Notice to Customers

Dear Valued Customer:

BFI is offering a new two year contract to  
all small containerized solid waste hauling  
customers with service locations in the  
countries of Dubuque and Jackson, IA. We  
would like to take this opportunity to offer  
this contract to you. Of course, if you prefer,  
you can continue with your existing contract.

In most cases, this new contract will have  
terms that are more advantageous to  
customers than their current contracts. This  
new contract has the following features:

- an initial term of no longer than 2 years  
(unless you request a longer term);
- a renewal term of 1 year;
- you can choose not to renew the contract  
by simply giving us notice at any time up  
to 30 days prior to the end of your term;
- if you request a contract with a term longer  
than 2 years, you can cancel that contract  
by giving us notice at any time up to 30  
days prior to the end of the first 2 years;
- you can choose to terminate the contract at  
any other time, but you will be required to  
pay, as liquidated damages, no more than  
3 times the greater of your prior monthly  
or average monthly charge. If you've been  
a customer continuously for more than 1  
year, the liquidated damages would be  
reduced to 2 times the greater of your prior  
monthly or average monthly charge;
- you will be able to choose on the contract  
which specific types of waste hauling  
services you would like us to perform.

You may obtain a new contract containing  
these terms by calling [insert BFI contact and  
number].

If you prefer, you may continue with your  
existing contract. If you retain your existing  
contract, we will not enforce any terms that  
are inconsistent with the new form contract  
terms.

If you have any questions, please call [BFI  
contact person and phone number.]

## EXHIBIT D

REMINDER: Your contract will  
automatically renew 90 days from the date of  
this notice unless we receive your  
cancellation within 60 days from the date of  
this notice.

You may also obtain a new form contract  
for solid waste hauling services with some  
terms more advantageous to you than your  
current contract. We will send you a copy on  
request.

Existing contract terms inconsistent with  
the new form will not be enforced against  
you.

United States District Court for the  
District of Columbia

In the matter of *United States of America*,  
Plaintiff, v. *Browning-Ferris Industries of  
Iowa, Inc., Browning-Ferris Industries of  
Tennessee, Inc., and Browning-Ferris  
Industries Inc.*, Defendants.

[Case Number: 1-96-V00297]

JUDGE: Thomas Pennfield Jackson.

DATE STAMP: February 15, 1996.

## Competitive Impact Statement

The United States, pursuant to  
Section 2(b) of the Antitrust Procedures  
and Penalties Act ("APPA"), 15 U.S.C.  
§ 16(b)-(h), files this Competitive  
Impact Statement relating to the  
proposed Final Judgment submitted for  
entry in this civil proceeding.

### I. Nature and Purpose of the Proceeding

On February 15, 1996, the United  
States filed a civil antitrust Complaint to  
prevent and restrain Browning-Ferris  
Industries, Inc. ("BFI"), Browning-Ferris  
Industries of Iowa, Inc. ("BFII"), and  
Browning-Ferris Industries of  
Tennessee, Inc. ("BFIT") from using  
contracts that have restrictive and  
anticompetitive effects on small  
containerized hauling service markets in  
Memphis and Dubuque, in violation of  
Section 2 of the Sherman Act, 15 U.S.C.  
2. As alleged in the Complaint,  
Defendants have attempted to  
monopolize small containerized hauling  
service in the Memphis and Dubuque  
geographic markets by using and  
enforcing contracts containing  
restrictive provisions to maintain and  
enhance their existing market power  
there.

The Complaint alleges that: (1)  
Defendant BFIT has market power in  
small containerized hauling service in  
the Memphis, TN market and Defendant  
BFII has market power in small  
containerized hauling service in the  
Dubuque, IA market; (2) Defendants,  
acting with specific intent, used and  
enforced contracts containing restrictive  
provisions to exclude and constrain  
competition and to maintain and  
enhance their market power in small  
containerized hauling service in those  
markets; (3) in the context of their large  
market shares and market power,  
Defendants' use and enforcement of  
those contracts in the Memphis and  
Dubuque markets has had  
anticompetitive and exclusionary effects  
by significantly increasing barriers to  
entry facing new entrants and barriers to  
expansion faced by small incumbents;  
(4) Defendants' market power is  
maintained and enhanced by their use  
and enforcement of those contracts; and,  
(5) as a result, there is a dangerous  
probability that Defendants will achieve

monopoly power in the Memphis and Dubuque markets.

In its Complaint, Plaintiffs seeks, among other relief, a permanent injunction preventing Defendants from continuing any of the anticompetitive practices alleged to violate the Sherman Act, and thus affording fair opportunities for other firms to compete in small containerized hauling service in the Memphis and Dubuque markets.

The United States and Defendants also have filed a Stipulation by which the parties consented to the entry of a proposed Final Judgment designed to eliminate the anticompetitive effects of Defendants' actions in the Memphis and Dubuque markets. Under the proposed Final Judgment, as explained more fully below, in dealing with small-container customers in the Memphis and Dubuque markets, Defendants would only be permitted to enter into contracts containing significantly less restrictive terms than the contracts they now use in those markets. Furthermore, Defendants would be prohibited from enforcing provisions in existing contracts that are inconsistent with the Final Judgment.

The United States and the Defendants have stipulated that the proposed Final Judgment may be entered after compliance with the APPA. Entry of the proposed Final Judgment would terminate the action, except that the Court would retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and to punish violations thereof.

## II. Description of the Events Giving Rise to the Alleged Violation

Browning-Ferris Industries, Inc. ("BFI"), is the world's second-largest company engaged in the solid waste hauling and disposal business, with operations throughout the United States. Browning-Ferris Industries, Inc. had revenues of approximately \$4 billion in its 1994 fiscal year.

Browning-Ferris Industries of Iowa, Inc. ("BFII") is a subsidiary of BFI with its principal offices in Des Moines, IA. It is the largest solid waste hauling and disposal company in the Dubuque, IA market. BFII had revenues of over \$2.6 million in its 1994 fiscal year.

Browning-Ferris Industries of Tennessee, Inc., ("BFIT") is also a subsidiary of BFI. It has its principal offices in Memphis, TN. It is the largest solid waste hauling and disposal company in the Memphis, TN market. BFIT had revenues over \$40.9 million in its 1994 fiscal year.

### A. The Solid Waste Hauling Industry

Solid waste hauling involves the collection of paper, food, construction material and other solid waste from homes, businesses and industries, and the transporting of that waste to a landfill or other disposal site. These services may be provided by private haulers directly to residential, commercial and industrial customers, or indirectly through municipal contracts and franchises.

Service to commercial customers accounts for a large percentage of total hauling revenues. Commercial customers include restaurants, large apartment complexes, retail and wholesale stores, office buildings, and industrial parks. These customers typically generate a substantially larger volume of waste than do residential customers. Waste generated by commercial customers is generally placed in metal containers of one to ten cubic yards provided by their hauling company. One to ten cubic yards containers are called "small containers." Small containers are collected primarily by front-end load vehicles that lift the containers over the front of the truck by means of a hydraulic hoist and empty them into the storage section of the vehicle, where the waste is compacted. Service to commercial customers that use small containers is called "small containerized hauling service."

Solid waste hauling firms also provide service to residential and industrial (or "roll-off") customers. Residential customers, typically households and small apartment complexes that generate small amounts of waste, use noncontainerized solid waste hauling service, normally placing their waste in plastic bags, trash cans, or small plastic containers at curbside.

Industrial or roll-off customers include factories and construction sites. These customers either generate noncompactible waste, such as concrete or building debris, or very large quantities of compactible waste. They deposit their waste into very large containers (usually 20 to 40 cubic yards) that are loaded onto a roll-off truck and transported individually to the disposal site where they are emptied before being returned to the customers' premises. Some customers, like shopping malls, use large, roll-off containers with compactors. This type of customer generally generates compactible trash similar to the waste of commercial customers, but in much greater quantities; it is more economical for this type of customer to use roll-off service with a compactor than to use a number

of small containers picked up multiple times a week.

### B. Relevant Product Market

The relevant product market is a small containerized hauling service. There are no practical substitutes for this service. Small containerized hauling service customers will not generally switch to noncontainerized service in the event of a price increase, because it is too impractical and more costly for those customers to bag and carry their volume of trash to the curb for hand pick-up. Similarly, roll-off service is much too costly and the container takes up too much space for most small containerized hauling service customers. Only customers that generate the largest volumes of compactible solid waste can economically consider roll-off service, and for customers that do generate large volumes of waste, roll-off service is usually the only viable option.

### C. Relevant Geographic Markets

The relevant geographic markets are the Memphis market and the Dubuque market. Small containerized solid waste hauling services are generally provided in very localized areas. Route density (a large number of customers that are close together) is necessary for small containerized solid waste hauling firms to be profitable. In addition, it is not economically efficient for heavy trash hauling equipment to travel long distances from customers without collecting significant amounts of waste. Thus, it is not efficient for a hauler to serve major metropolitan areas from a distant base. Haulers, therefore, generally establish garages and related facilities within each major local area served.

### D. Defendants' Attempt to Monopolize

Defendant BFIT has market power in small containerized hauling service in the Memphis market. BFIT has maintained a very high market share for over 10 years—consistently in excess of 60 percent.

Defendant BFII has market power in small containerized hauling service in the Dubuque market. BFII entered that market in 1979. It maintains a very high market share—in excess of 60 percent.

There are substantial barriers to entry and to expansion into the small containerized hauling markets in Memphis and in Dubuque. A new entrant or small incumbent hauler must be able to achieve minimum efficient scale to be competitive. First, it must be able to generate enough revenues to cover significant fixed costs and overhead.

Second, a new entrant or small incumbent hauler must be able to obtain enough customers to use its trucks efficiently. For example, it is not efficient to use a truck half a day because the firm doesn't have enough customers to fill up the truck.

Third, a new entrant or small incumbent hauler needs to obtain customers that are close together on its routes (called "route density"). Having customers close together enables a company to pick up more waste in less time (and generate more revenues in less time). The better a firm's route density, the lower its operating costs.

Until a firm overcomes these barriers, the new entrant or small incumbent will have higher operating costs than Defendants in the relevant geographic markets, may not operate at a profit, and will be unable effectively to constrain pricing by Defendants in those markets.

Defendant BFIT in the Memphis market and Defendant BFII in the Dubuque market have entered into written contracts with the vast majority of their small containerized hauling customers. Many of these contracts contain terms that, when taken together in the relevant markets where Defendants have market power, make it more difficult and costly for customers to switch to a competitor of Defendants and allows Defendants to bid to retain customers approached by a competitor.

The contracts enhance and maintain Defendants' market power in the Memphis and Dubuque markets by significantly raising the cost and time required by a new entrant or small incumbent firm to build its customer base and obtain efficient scale and route density. Therefore, Defendants' use and enforcement of these contracts in the Memphis and Dubuque markets raise barriers to entry and expansion in those markets. Those contract terms are:

a. A provision giving Defendants the exclusive right or opportunity to collect and dispose of all the customers' solid waste and recyclables;

b. An initial term of three years;

c. A renewal term of three years that automatically renews unless the customer sends Defendants a written notice of cancellation by certified mail more than 60 days from the end of the initial or renewal term; and

d. A term that requires a customer that terminates the contract at any other time to pay Defendants, as liquidated damages, its most recent monthly charge times six (if the remaining term is six or more months) or its most recent monthly charge times the number of months remaining under the contract (if the remaining term is less than six months).

The appearance and format of the contracts also enhances Defendants' ability to use the contracts to maintain their market power in these markets. The provisions that make it difficult for a customer to switch to a competing hauler are not obvious to customers in the relevant markets. The document is not labeled "Contract" so its legally binding nature is not always apparent to the customer. Also, all the restrictive provisions mentioned above are in small print and the provision described in (d) is on the back of the document.

Defendants' use and enforcement of the contracts described above in the Memphis and Dubuque markets have raised the barriers already faced by new entrants and small existing firms in those markets. Defendants' use and enforcement of the contracts has reduced the likelihood that customers will switch to a Defendant's competitor. Given Defendants' market power, this has made it more difficult for competitors to achieve efficient scale, obtain sufficient customers to use their trucks efficiently, and develop sufficient route density to be profitable and to constrain Defendants' pricing in those markets.

### III. Explanation of the Proposed Final Judgment

The proposed Final Judgment will end the unlawful practices currently used by Defendants to perpetuate and enhance their market power in the Memphis and Dubuque markets. It requires Defendants to offer less restrictive contracts to small containerized hauling customers in the Memphis and Dubuque markets.<sup>1</sup>

In particular, Paragraphs IV (A) and (B) prohibit Defendants from entering into contracts containing the type of restrictive terms described above. Paragraphs IV (C), (D), (E), and (F) are designed to bring existing contracts into compliance with the proposed Final Judgment on an expeditious basis.

#### *A. Prohibition of Contract Terms and Formats*

The contracts used most frequently by Defendants in the relevant markets have an initial term of three years and renew automatically and perpetually for

additional three-year terms unless cancelled by the customer. In these markets, given that the Defendants have market power and a vast majority of their existing customers are subject to such contracts, the long initial term and long renewal terms prevent new entrants and small incumbents, no matter how competitive, from quickly obtaining enough customers that are close together to be profitable. Shortening the initial term and the renewal term will allow competitors to compete for more of the customer base each year and, if they compete effectively, to obtain efficient scale and route density more quickly. This, in turn, will enhance competition in the relevant markets and will help offset Defendants' market power.

Paragraph IV(A)(1) prohibits Defendants from using contracts for service locations in the Memphis and Dubuque markets that have an initial term longer than two years, except under certain very limited circumstances.

A contract with an initial term in excess of two years in the relevant markets is permitted, under limited circumstances, pursuant to Paragraph IV(B) of the proposed Final Judgment, but the contracts must otherwise conform to the Final Judgment. The United States is aware that some customers, for valid business reasons such as long-term price assurance, want contracts with an initial term longer than two years. Paragraph IV(B) is intended to permit customers who want them to have such contracts, while ensuring that customers who have not made such a choice do not, nevertheless, find themselves with long contracts. Under Paragraph IV(B)(1), Defendants may sign a contract of longer than two years with a customer, but only if the Defendants have not implemented any organized, management-authorized sales or marketing plan designed, through pricing or other incentives to induce customers to use other than the form contracts Defendants are required to offer by the proposed Final Judgment. Even if the customer signs a contract with an initial term longer than two years, the customer retains the right to terminate that contract at the end of the first 2 years without payment of any liquidated damages, pursuant to Paragraph IV(B)(2). Paragraph IV(B) was included to give Defendants the ability to contract with customers who truly want a longer term, for the United States anticipates that contracts with initial terms longer than two years will be the exception, not the rule.

<sup>1</sup> The proposed Final Judgment applies to all contracts entered into by Defendants with customers for service locations in the relevant markets except contracts described in Paragraph IV(G). Contracts awarded to Defendants by municipal or government entities as a result of a formal request for bids or a formal request for proposals need not contain the provisions dictated by the proposed Final Judgment. These contracts were excluded from the decree to assure that competition for such bids would not be adversely affected by preventing Defendants from bidding.



Paragraph IV(A)(2) prohibits Defendants from signing a contract with a renewal term longer than one year in length, down from the three-year renewal term used as a standard in the Memphis and Dubuque markets.

Paragraph IV(A)(3) increases the period of time that a customer may notify Defendants of its intention not to renew the contract from a period ending 60 days before the end of any initial or renewal term to a period ending 30 days before the end of any such term. This allows the customer to make a decision concerning renewal closer to the end of the contract term. A customer is more likely to consider whether or not it wants its existing contract renewed the closer that customer is to the end of the contract term. Paragraph IV(A)(3) assures that a customer will be able to choose not to renew its contract up to 30 days from the end of the contract term. Paragraph IV(A)(3) also eliminates the requirement that a customer give its nonrenewal notice in writing and send it to Defendants by certified mail. A telephone call or letter is sufficient under the proposed Final Judgment. These changes in the notification provisions make it easier for the customer not to renew within the terms of the contract. This, in turn, enhances customer choice and enables small incumbents to compete for more customers.

A liquidated damages provision is intended to allow a seller to recover otherwise unrecoverable costs where the amount of the damage resulting from a breach of contract is difficult to determine. Defendants do incur some unrecoverable costs, including sales costs, in contracting with customers for small containerized solid waste hauling services. The contract currently most widely used by Defendants in the relevant markets contains the following liquidated damages provision for early termination: the customer must pay six times its most recent monthly charge unless the contract has a remaining term of less than six months, in which case the customer pays its most recent monthly charge times the number of months remaining in its contract term. If this case went to trial, the United States believes it could prove that these liquidated damages far surpass the contracting costs the Defendants incur, and that, in the relevant markets where Defendants have market power, Defendants have threatened to enforce such liquidated damages provisions with the effect that customers did not switch to new entrants and small incumbents when they desired to do so. In the presence of market power, the threat of enforcing large liquidated

damages provisions can deter sufficient customers from switching to a competitor and harm competition.

Paragraphs IV(A) (4) and (5) reduce the amount of liquidated damages Defendants can collect from a customer. The liquidated damages Defendants may collect from a customer in the relevant markets during the first year of the initial term of a customer's contract are reduced to the greater of three times the customer's prior monthly charge or average monthly charge over the prior six months. A firm that has been a customer of a Defendant for a continuous period in excess of one year can be required to pay Defendants no more than two times the greater of the customer's prior monthly charge or average monthly charge over the prior six months. The changes made in the liquidated damages provisions make it less expensive (and therefore more likely) that a customer can switch to a competing hauler should it choose to do so during the contract term. Defendants have incurred costs to sign small containerized solid waste hauling customers to contracts. However, as customers pay their monthly bills over time, the unrecovered amount of those costs decreases. That fact is reflected in the proposed Final Judgment by the reduction of the liquidated damages Defendants may collect once a firm has been Defendants' customer for more than one year.

The contracts predominantly used by Defendants in the relevant markets currently give Defendants the exclusive right to perform all of a customer's solid waste hauling services and recycling, just because the customer has signed a contract for small containerized solid waste hauling service. Those contracts also contain a provision requiring the customer to give BFI the opportunity to provide the customer's need for additional services during the contract term.<sup>2</sup> Paragraph IV(A)(7) of the proposed Final Judgment prohibits these provisions in the relevant markets. Instead, it provides that Defendants may perform only those services a customer selects. Defendants may perform all types of solid waste hauling services and recycling for a customer, but only if the customer chooses to have Defendants do so by affirmatively indicating its desire for such additional

<sup>2</sup> That provision reads: "OPPORTUNITY TO PROVIDE ADDITIONAL SERVICES. BFI values the opportunity to meet all of Customer's nonhazardous waste collection and disposal needs. Customer will provide BFI the opportunity to meet those needs and to provide, on a competitive basis, any additional nonhazardous waste disposal and collection services during the term of this Agreement."

services on the front of the contract.<sup>3</sup> The United States does not intend this provision to prohibit Defendants from requiring that it be the exclusive supplier of any one type of service for which it contracts with a customer. For example, if a customer contracts with Defendants to perform small containerized solid waste hauling service at a specific service location, Defendants may require that it be the exclusive supplier for that service at the location.

Paragraph IV(A)(6) of the proposed Final Judgment requires Defendant to change the appearance and format of its contracts in the relevant markets. If this case went to trial, evidence from customers in those markets would show that some of them were not aware they had signed legally binding documents. Therefore, the proposed Final Judgment requires that the document be labeled "CONTRACT FOR SOLID WASTE SERVICES" in large letters. Furthermore, evidence from customers in the relevant markets would show that the contractual provisions that enable a firm with market power to restrict customers from switching to a competitor are in small print and not readily noticed by all customers. The proposed Final Judgment requires that the contracts used in the relevant markets be easily readable in formatting and type-face.

#### *B. Transition Rules*

In the Stipulation consenting to the entry of the proposed Final Judgment, Defendants agreed to abide by the provisions of the proposed Final Judgment immediately upon the filing of the Complaint, *i.e.*, as of February 15, 1996. Among other things, the transition provisions described herein will require Defendants to abide by the foregoing limitations and prohibitions when entering into any contracts with new small containerized hauling customers after February 15, 1996. Certain additional provisions of the proposed Final Judgment also apply to existing customer contracts that are inconsistent with the proposed Final Judgment's requirements for new customer contracts.

Under Paragraph IV(C), Defendants must offer contracts that conform with Paragraphs IV (A) or (B) of the proposed Final Judgment to all new customers with service locations in the Memphis and Dubuque markets beginning today,

<sup>3</sup> The United States anticipates that the customer should be able to affirmatively indicate its choice of service types by checking a box, or writing in the type of service it wants on the front of the contract, or by some similar mechanism.



the date of the filing of the executed Stipulation.

Under Paragraph IV(D), within ninety (90) days following entry of the Final Judgment Defendants must notify existing customers with service locations in the Memphis market who have an initial term longer than two years and do not otherwise comply with the proposed Final Judgment of their right to sign a new contract complying with the proposed Final Judgment. Defendants must send a similar notice within thirty (30) days following entry of the Final Judgment for customers with service locations in the Dubuque market. These notices must also inform any customers choosing to retain their existing contracts that no provisions inconsistent with the proposed Final Judgment will be enforced against them. The Final Judgment provides more time for Defendants to notify customers in Memphis than in Dubuque because Defendants have vastly more customers in Memphis than in Dubuque; they will need a longer time to provide the required notices and answer consumer inquiries in Memphis than they will need in Dubuque. With regard to municipal and government entities, Defendants are not required to notify those entities with nonconforming contracts that were awarded on the basis of a formal request for bids or a formal request for proposals issued by the customer.

Paragraph IV(E) requires Defendants to give an additional notice in the form of a reminder to any customer subject to a nonconforming contract that enters a renewal term 120 days or more after the entry to the proposed Final Judgment. Defendants must send the reminder to each such customer ninety days or more prior to the effective date of the renewal term. The reminder informs the customer that it must cancel its contract by a certain date or the contract will renew. It also reminds the customer that it may enter into a new contract conforming to the proposed Final Judgment on request and that terms in the customer's existing contract that are inconsistent with the new form will not be enforced against it. Defendants may send this reminder as part of a monthly bill, as long as it appears on a separate page and in large print so that it will be noticeable.

Under Paragraph IV(F), Defendants may enforce existing contract provisions only to the extent consistent with the Final Judgment upon entry of the Final Judgment by the Court.

Finally, under paragraphs IV (G) and (H), the proposed Final Judgment makes clear that contracts awarded by municipal or government entities on the

basis of a formal request for bids or proposals issued by the customer need not comply with Paragraphs IV(A)–(F). Moreover, nothing in the proposed Final Judgment requires Defendants to do business with any customer.

Paragraphs IV (C)–(F) further two consistent goals. Opportunities for competition in small containerized hauling service in the relevant markets will be fostered by a rapid end to the provisions that significantly raise entry barriers in the relevant markets. At the same time, the transition rules avoid creating any unnecessary disruption of the customers' trash hauling service that might result from voiding all nonconforming contracts. Existing customers are not required to terminate or amend their existing contracts with Defendants; the choice belongs to the customer. However, Defendants may not enforce against any customer any provision inconsistent with the proposed Final Judgment.

To ensure that existing customers learn of their rights under the proposed Final Judgment, Paragraphs IV (D) and (E) require Defendants to notify customers of their rights under the Final Judgment and remind them annually of their right to terminate their existing contract or to sign a new contract form.

#### C. Enforcement

Section V of the proposed Final Judgment establishes standards and procedures by which the Department of Justice may obtain access to documents and information from Defendants related to their compliance with the proposed Final Judgment.

#### D. Duration

Section VI of the proposed Final Judgment provides that the Final Judgment will expire on the tenth year after its entry. Jurisdiction will be retained by the Court to conduct further proceedings relating to the Final Judgment, as specified in Section VI.

#### IV. Remedies Available To Potential Private Litigants

Section 4 of the Clayton Act (15 U.S.C. 15) provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages the person has suffered, as well as costs and reasonable attorneys' fees. Entry of the proposed Final Judgment will neither impair nor assist the bringing of any private antitrust damage action. Under the provisions of Section 5(a) of the Clayton Act (15 U.S.C. 16(a)), the proposed Final Judgment has no *prima facie* effect in

any subsequent private lawsuit that may be brought against defendants.

#### V. Procedures Available for Modification of the Proposed Final Judgment

The United States and Defendants have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least 60 days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within sixty (60) days of the date of publication of this Competitive Impact Statement in the Federal Register. The United States will evaluate and respond to the comments. All comments will be given due consideration by the Department of Justice, which remains free to withdraw its consent to the proposed Judgment at any time prior to entry. The comments and the response of the United States will be filed with the Court and published in the Federal Register.

Written comments should be submitted to: Anthony V. Nanni, Chief, Litigation I Section, Antitrust Division, United States Department of Justice, 1401 H Street, N.W., Suite 4000, Washington, D.C. 20530. The proposed Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

#### VI. Alternatives to the Proposed Final Judgment

The United States considered, as an alternative to the proposed Final Judgment, litigation against Defendants. The United States could have brought suit and sought preliminary and permanent injunctions against the use and enforcement of these contracts by Defendants in the relevant markets. The United States is satisfied, however, that the relief outlined in the proposed Final Judgment will eliminate Defendants' ability to use restrictive and anticompetitive contracts to maintain and enhance their market power in the relevant markets. The United States believes that these contracts will no longer inhibit the ability of a new entrant to compete with the Defendants. The relief sought will allow new entry

and expansion by existing firms in those markets.

#### VII. Standard of Review Under the APPA for Proposed Final Judgment

The APPA requires that proposed consent judgments in antitrust cases brought by the United States be subject to a sixty-day comment period, after which the court shall determine whether entry of the proposed Final Judgment "is in the public interest." In making that determination, the court may consider—

(1) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration or relief sought, anticipated effects of alternative remedies actually considered, and any other considerations bearing upon the adequacy of such judgment;

(2) the impact of entry of such judgment upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. 16(e). As the D.C. Circuit recently held, this statute permits a court to consider, among other things, the relationship between the remedy secured and the specific allegations set forth in the government's complaint, whether the decree is sufficiently clear, whether enforcement mechanisms are sufficient, and whether the decree may positively harm third parties. See *United States v. Microsoft*, 56 F.3d 1448, 1462 (D.C. Cir. 1995). In conducting this inquiry, "the Court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process."<sup>4</sup>

Rather, absent a showing of corrupt failure of the government to discharge its duty, the Court, in making its public interest finding, should . . . carefully consider the explanations of the government in the competitive impact statement and its responses to comments in order to determine whether those explanations are reasonable under the circumstances.

<sup>4</sup> 119 Cong. Rec. 24598 (1973). See *United States v. Gillette Co.*, 406 F. Supp. 713, 715 (D. Mass. 1975). A "public interest" determination can be made properly on the basis of the Competitive Impact Statement and Response to Comments filed pursuant to the APPA. Although the APPA authorizes the use of additional procedures, 15 U.S.C. § 16(f), those procedures are discretionary. A court need not invoke any of them unless it believes that the comments have raised significant issues and that further proceedings would aid the court in resolving those issues. See H.R. Rep. 93-1463, 93rd Cong. 2d Sess. 8-9, reprinted in (1974) U.S. Code Cong. & Ad. News 6535, 6538.

*United States v. Mid-America Dairymen, Inc.*, 1977-1 Trade Cas. ¶ 61,508, at 71,980 (W.D. Mo. 1977).

The Court's inquiry, under the APPA, is whether the settlement is "within the reaches of the public interest."<sup>5</sup> The proposed Final Judgment enjoins the Defendants' continued use of overly restrictive contract terms and opens local markets to increased competition, thus effectively furthering the public interest.

#### VIII. Determinative Documents

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Dated: February 15, 1996.

Respectfully submitted,

Nancy H. McMillen,

Peter H. Goldberg,

DC Bar #055608,

Evangelina Almirantearena,

Attorneys, Antitrust Division, U.S.

Department of Justice, 1401 H. Street, N.W.,

Suite 4000, Washington, D.C. 20530, (202)

307-5777.

#### Certification of Service

I hereby certify that a copy of the foregoing has been served upon Browning-Ferris Industries of Iowa, Inc., Browning-Ferris Industries of Tennessee, Inc., and Browning-Ferris Industries, Inc., by placing a copy of this Competitive Impact Statement in the U.S. mail, directed to each of the above-

named parties at the addresses given below, this 15th day of February, 1996.

Rufus Wallingford,

Esquire, Executive Vice President and General Counsel,

Lee Keller,

Esquire, Senior Litigation Counsel, Browning-Ferris Industries, Inc., 757 North Eldridge Street, Houston, TX 77079.

David Foster,

Esquire, Fulbright & Jaworski, L.L.P., 801 Pennsylvania Avenue, NW, Market Square, Washington, D.C. 20004-2604.

Richard N. Carrell,

Esquire, Fulbright & Jaworski, L.L.P., 1301 McKinney, Suite 5100, Houston, Texas 77010-3095.

Nancy H. McMillen,

Attorney, U.S. Department of Justice, Antitrust Division, 1401 H. Street, N.W., Suite 4000, Washington, D.C. 20530, (202) 307-5777.

United States District Court for the District of Columbia

In the matter of *United States of America*, Plaintiff, v. *Browning-Ferris Industries of Iowa, Inc., Browning-Ferris Industries of Tennessee, Inc., and Browning-Ferris Industries, Inc.*, Defendants.

[Case number: 1-96-V00297]

Judge: Thomas Penfield Jackson

Deck Type: Antitrust.

Date Stamp: Feb. 15, 1996.

Motion of United States to Exclude Case From all Discovery Requirements and to Follow the Procedures of the Antitrust Procedures and Penalties Act

The United States of America hereby moves the Court for an order to exclude this case from all discovery requirements under the Federal Rules of Civil Procedure given that the disposition of a negotiated civil antitrust case brought and settled by the United States is governed by the Antitrust Procedures and Penalties Act, 15 U.S.C. 16 (b)-(h) [hereinafter "the APPA"].

As set forth below, the parties have consented to the entry of the proposed Final Judgment without trial or adjudication of any issue of fact or law, and without the Final Judgment constituting any evidence against or an admission by any party with respect to any such issue. Pursuant to the procedures of the APPA, discovery between the parties is unnecessary and would be contrary to the intentions of the parties. Therefore, the United States respectfully requests that the Court enter the attached Order which excludes the case from discovery requirements of the Federal Rules of Civil Procedure, and states that the disposition of the case will be consistent with the APPA.

1. On February 15, 1996, the United States filed a Complaint and a

<sup>5</sup> *United States v. Bechtel*, 648 F.2d 660, 666 (9th Cir.), cert. denied, 454 U.S. 1083 (1981); see *United States v. BNS, Inc.*, 858 F.2d 456, 463 (9th Cir. 1988); *United States v. National Broadcasting Co.*, 449 F. Supp. 1127, 1143 (C.D. Cal. 1978); *United States v. Gillette Co.*, 406 F. Supp. at 716. See also *United States v. American Cyanamid Co.*, 719 F.2d 558, 565 (2d Cir. 1983), cert. denied, 465 U.S. 1101 (1984); *United States v. American Tel. and Tel Co.*, 552 F. Supp. 131, 150 (D.D.C. 1982), *aff'd sub nom. Maryland v. United States*, 460 U.S. 1001 (1983) quoting *United States v. Gillette Co.*, supra, 406 F. Supp. at 716; *United States v. Alcan Aluminum, Ltd.*, 605 F. Supp. 619, 622 (W.D. Ky 1985).

Stipulation by which the parties agreed to the Court's entry of an attached proposed Final Judgment following compliance with the APPA.

2. The United States also filed on February 15, 1996, a Competitive Impact Statement as required by 15 U.S.C. 16(b).

3. The APPA also requires the United States to publish a copy of the proposed Final Judgment and the Competitive Impact Statement in the Federal Register. It further requires the publication of summaries of the terms of the proposed Final Judgment and the Competitive Impact Statement in at least two newspapers of general circulation. This notice will inform members of the public that they may submit comments about the Final Judgment to the United States Department of Justice, Antitrust Division. 15 U.S.C. 16 (b)-(c).

4. Following such publication in the newspapers and Federal Register, a sixty-day waiting period will begin. During this time, the United States will consider, and at the close of that period respond to, any public comments that it receives. It will publish the comments and its responses in the Federal Register. 15 U.S.C. 16(d).

5. After the expiration of the sixty-day period, the United States will file with the Court the comments, the Government's responses, and a Motion For Entry of the Final Judgment. 15 U.S.C. 16(d).

6. After the filing of the Motion for Entry of the Final Judgment, the Court may enter the Final Judgment without a hearing, if it finds that the Final Judgment is in the public interest. 15 U.S.C. 16 (e)-(f).

7. The parties fully intend to comply with the requirements of the APPA.

As stated above, the Antitrust Procedures and Penalties Act governs the disposition of civil antitrust cases brought and settled by the United States. Discovery between the parties, which have consented to the proposed settlement filed with the Court, is unnecessary. Accordingly, the attached Order is justified and should be entered by the Court.

Respectfully submitted,  
Nancy H. McMillen,  
*Trial Attorney, U.S. Department of Justice, Antitrust Division, 1401 H Street, NW., Suite 4000, Washington, DC 20530, Tel: (202) 307-5777.*

#### Certificate of Service

I hereby certify that on February 15, 1996, a true and correct copy of the foregoing has been served on the parties below by placing a copy of this MOTION OF UNITED STATES TO EXCLUDE CASE FROM ALL

DISCOVERY REQUIREMENTS AND TO FOLLOW THE PROCEDURES OF THE ANTITRUST PROCEDURES AND PENALTIES ACT in the U.S. Mail, postage prepaid, to the address given below:

For Defendants Browning-Ferris Industries of Iowa, Inc., Browning-Ferris Industries of Tennessee, Inc., and Browning-Ferris Industries, Inc.:

David Foster, *Esquire*,  
*Fulbright & Jaworski, L.L.P., 801 Pennsylvania Ave., N.W., Market Square, Washington, D.C. 20004-2604.*

Rufus Wallingford, *Esquire*,  
*Executive Vice President and General Counsel*,

Lee Keller, *Esquire*,  
*Senior Litigation Counsel, Browning-Ferris Industries, Inc., 757 North Eldridge Street, Houston, TX 77079.*

Richard N. Carrell, *Esquire*,  
*Fulbright & Jaworski, L.L.P., 1301 McKinney, Suite 5100, Houston, TX 77010-3095.*

Nancy H. McMillen,  
*Trial Attorney, U.S. Department of Justice, Antitrust Division, 1401 H Street, N.W., Suite 4000, Washington, D.C. 20530, (202) 307-5777.*

United States District Court for the District of Columbia

In the matter of *United States of America, Plaintiff, v. Browning-Ferris Industries of Iowa, Inc., Browning-Ferris Industries of Tennessee, Inc., and Browning-Ferris Industries, Inc., Defendants.*

[Civil Action No.: 1-96-V00297]

Filed: Feb. 15, 1996.

Order Excluding Case From All Discovery Requirements and To Follow the Procedures of the Antitrust Procedures and Penalties Act

Plaintiff, the United States of America, has moved the Court to exclude this case from all discovery requirements under the Federal Rules of Civil Procedure given that the disposition of negotiated civil antitrust consent decrees are governed by the *Antitrust Procedures and Penalties Act*, 15 U.S.C. 16 (b)-(h). The Court is of the opinion that this motion should be granted.

It is therefore ORDERED that this case is excluded from all discovery requirements under the Federal Rules of Civil Procedure.

It is also therefore ORDERED that the procedures to be followed in this case shall be consistent with the *Antitrust Procedures and Penalties Act*, 15 U.S.C. § 16 (b)-(h).

Dated: \_\_\_\_\_

UNITED STATES DISTRICT JUDGE.

[FR Doc. 96-5033 Filed 3-4-96; 8:45 am]

BILLING CODE 4410-01-M

#### **United States v. Waste Management, Inc.; Proposal Final Judgment and Competitive Impact Statement**

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)-(h), that a proposed Final Consent Judgment, Stipulation, and Competitive Impact Statement have been filed with the United States District Court for the Southern District of Georgia in the above-captioned case.

On February 15, 1996, the United States filed a civil antitrust Complaint to prevent and restrain Waste Management, Inc. ("WMI"), Waste Management of Georgia, Inc. ("WMG"), d/b/a Waste Management of Savannah, and Waste Management of Louisiana, Inc. ("WML"), d/b/a Waste Management of Central Louisiana from maintaining and enhancing their market power by using contracts that have restrictive and anticompetitive effects, in violation of Section 2 of the Sherman Act, 15 U.S.C. 2.

The Complaint alleges that: (1) Defendant WMG has market power in small containerized hauling service in the Savannah, GA market and Defendant WML has market power in small containerized hauling service in the Central Louisiana market; (2) Defendants, acting with specific intent, used and enforced contracts containing restrictive provisions to exclude and constrain competition and to maintain and enhance their market power in small containerized hauling service in those markets; (3) in the context of their large market shares and market power, Defendants' use and enforcement of those contracts in the Savannah and Central Louisiana markets has had anticompetitive and exclusionary effects by significantly increasing barriers to entry facing new entrants and barriers to expansion faced by small incumbents; (4) Defendants' market power is maintained and enhanced by their use and enforcement of those contracts; and, (5) as a result, there is a dangerous probability that Defendants will achieve monopoly power in the Savannah and Central Louisiana markets.

The proposed Final Consent Judgment would require that, in dealing with small-container customers in the Savannah and Central Louisiana markets, Defendants only to enter into contracts containing significantly less restrictive terms than the contracts they now have in use in those markets. Specifically, the Defendants will be

prohibited from using any contract with small-container customers in the Savannah and Central Louisiana markets that:

(1) Has an initial term longer than two years (unless a longer term is requested by the customer and other conditions are met);

(2) Has any renewal term longer than one year;

(3) Requires the customer give notice of termination more than 30 days prior to the end of a term;

(4) Requires the customer to pay liquidated damages over 3 times the greater of its prior monthly charge or its average monthly charge during the first year of the initial term of the customer's contract, or over 2 times the greater of its prior monthly charge or its average monthly charge thereafter;

(5) Requires the customer to give Waste Management notice of any offer by or to another solid waste hauling firm or requires the customer to give it a reasonable opportunity the right to respond to such an offer for any period not covered by the contract ("right to compete" clause);

(6) Is not labeled "Service Contract" and is not easily readable; or

(7) Requires a customer to give Waste Management the right or opportunity to provide hauling services for all solid wastes and recyclables, unless the customer affirmatively indicates that is its desire. Furthermore, Defendants would be prohibited from enforcing provisions in existing contracts that are inconsistent with the Final Judgment.

Public comment is invited within the statutory 60-day period. Such comments will be published in the Federal Register and filed with the Court. Comments should be addressed to Anthony V. Nanni, Chief, Litigation I Section, U.S. Department of Justice, Antitrust Division, 1401 H St., N.W., Suite 4000, Washington, D.C. 20530 (phone 202/307-6576).

Rebecca P. Dick,  
Deputy Director of Operations.

United States District Court for the Southern District of Georgia, Savannah Division

In the matter of *United States of America*, Plaintiff, v. *Waste Management of Georgia, Inc.*, d/b/a *Waste Management of Savannah*, and *Waste Management of Louisiana, Inc.*, d/b/a *Waste Management of Central Louisiana*,

and *Waste Management, Inc.*, Defendants. Civil Action No.: CV496-35, filed: February 15, 1996.

### Stipulation

It is stipulated by and between the undersigned parties, by their respective attorneys, that:

1. The Court has jurisdiction over the subject matter of this action and over each of the parties hereto for the purposes of this proceeding. Defendant Waste Management of Georgia, Inc., d/b/a Waste Management of Savannah, transacts business and is found within the district. Defendants Waste Management of Louisiana, Inc., d/b/a Waste Management of Central Louisiana, and Waste Management, Inc. consent to personal jurisdiction in this proceeding. Defendants waive any objections as to venue and the parties stipulate that venue for this action is proper in the Southern District of Georgia;

2. The parties consent that a Final Judgment in the form hereto attached may be filed and entered by the Court, upon the motion of any party or upon the Court's own motion, at any time after compliance with the requirements of the Antitrust Procedures and Penalties Act (15 U.S.C. § 16(b)-(h)), and without further notice to any party or other proceedings, provided that Plaintiff has not withdrawn its consent, which it may do at any time before the entry of the proposed Final Judgment by serving notice thereof on the Defendants and by filing that notice with the Court; and

3. Defendants agree to be bound by the provisions of the proposed Final Judgment pending its approval by the Court. If the Plaintiff withdraws its consent or if the proposed Final Judgment is not entered pursuant to this Stipulation, this Stipulation shall be of no effect whatsoever, and the making of this Stipulation shall be without prejudice to any party in this or in any other proceeding.

Dated this 15th day of February, 1996.

Respectfully submitted,

For the Plaintiff the United States of America:

Anne K. Bingaman,  
Assistant Attorney General, Antitrust Division, U.S. Department of Justice.  
Lawrence R. Fullerton,

Deputy Assistant Attorney General.

Rebecca P. Dick,

Deputy Director of Operations.

Harry D. Dixon, Jr.,

United States Attorney, Southern District of Georgia.

Anthony V. Nanni,

Chief, Litigation I Section.

Nancy H. McMillen,

Peter H. Goldberg,

Evangelina Almirantarena,

Attorneys, U.S. Department of Justice,

Antitrust Division, City Center Building, Suite 4000, 1401 H Street, N.W., Washington, D.C. 20530, 202/307-5777.

For the Defendants Waste Management, Inc., Waste Management of Georgia, Inc., and Waste Management of Louisiana, Inc.: Robert Bloch, Esquire,

Mayer Brown & Platt, 2000 Pennsylvania Ave., N.W., Washington, D.C. 20006.

Michael Sennett, Esquire,

Bell, Boyd & Lloyd, 3 First National Plaza, 70 West Madison Street, Chicago, IL 60602.

Glen M. Darbyshire, Esquire (Georgia Bar #205210),

Hunter, Maclean, Exley & Dunn, P.C., 200 East St. Julian Street, Savannah, GA 31412-0048, (912) 236-0261.

United States District Court for the Southern District of Georgia, Savannah Division

In the matter of *United States of America*, Plaintiff, v. *Waste Management of Georgia, Inc.*, d/b/a *Waste Management of Savannah*, *Waste Management of Louisiana, Inc.*, d/b/a *Waste Management of Central Louisiana*, and *Waste Management, Inc.*, Defendants. Civil Action No.: CF496-35, filed: Feb. 15, 1996.

### Final Judgment

Whereas Plaintiff, United States of America, having filed its Complaint in this action on February 15, 1996, and Plaintiff and Defendants, by their respective attorneys, having consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law; and without this Final Judgment constituting any evidence or admission by any party with respect to any issue of fact or law;

Now, therefore, before any testimony is taken, and without trial or adjudication of any issue of fact or law, and upon consent of the parties, it is hereby

Ordered, adjudged and decreed as follows:

## I.

*Jurisdiction*

This Court has jurisdiction of the subject matter of this action and of the persons of the Defendants, Waste Management, Inc., Waste Management of Georgia, Inc., d/b/a Waste Management of Savannah, and Waste Management of Louisiana, Inc., d/b/a Waste Management of Central Louisiana. The Complaint states a claim upon which relief may be granted against the Defendants under Section 2 of the Sherman Act, 15 U.S.C. 2.

## II.

*Definitions*

As used in this Final Judgment:

(A) "Savannah market" means Chatham, Effingham, and Bryan Counties, Georgia.

(B) "Central Louisiana market" means Rapides, Natchitoches, Avoyelles, Red River, Winn, and Sabine Parishes, Louisiana.

(C) "Solid waste hauling" means the collection and transportation to a disposal site of trash and garbage (but not construction and demolition debris; medical waste; hazardous waste; organic waste; or special waste, such as contaminated soil, or sludge; or recyclable materials) from residential, commercial and industrial customers. Solid waste hauling includes hand pick-up, containerized pick-up, and roll-off service.

(D) "Defendants" means defendant Waste Management, Inc., a Delaware corporation with its headquarters in Oak Brook, Illinois, defendant Waste Management of Georgia, Inc. d/b/a Waste Management of Savannah, a Georgia corporation with offices in Savannah, Georgia, and defendant Waste Management of Louisiana, Inc., d/b/a Waste Management of Central Louisiana, a Louisiana corporation with offices in Alexandria, Louisiana, and includes their officers, directors, managers, agents, employees, successors, assigns, parents, and subsidiaries.

(E) "Small Container" means a 2 to 10 cubic yard container.

(F) "Small Containerized Solid Waste Hauling Service" means providing solid waste hauling service to customers by providing the customer with a Small Container that is picked up mechanically using a frontload, rearload, or sideload truck, and expressly excludes hand pick-up service, and service using a compactor attached to or part of a small container.

(G) "Customer" means a Small Containerized Solid Waste Hauling Service customer.

## III.

*Applicability*

This Final Judgment applies to Defendants and to their officers, directors, managers, agents, employees, successors, assigns, parents and subsidiaries, and to all other persons in active concert or participation with any of them who shall have received actual notice of this Final Judgment by personal service or otherwise. Nothing contained in this Final Judgment is or has been created for the benefit of any third party, and nothing herein shall be construed to provide any rights to any third party.

## IV.

*Prohibited Conduct*

Defendants are enjoined and restrained as follows:

(A) Except as set forth in paragraph IV (B) and (G), Defendants shall not enter into any contract with a Customer for a service location in the Savannah or Central Louisiana markets that:

(1) Has an initial term longer than two (2) years;

(2) Has any renewal term longer than one (1) year;

(3) Requires that the Customer give Defendants notice of termination more than thirty (30) days prior to the end of any initial term or renewal term;

(4) Requires that the Customer pay liquidated damages in excess of three times the greater of its prior monthly charge or its average monthly charge over the most recent six months during the first year of the initial term of the Customer's contract;

(5) Requires that the Customer pay liquidated damages in excess of two times the greater of its prior monthly charge or its average monthly charge over the most recent six months after the Customer has been a Customer of a Defendant for a continuous period in excess of one (1) year;

(6) Requires the Customer to give Defendants notice of any offer by or to another solid waste hauling firm or requires the Customer to give Defendants a reasonable opportunity to respond to such an offer for any period of covered by the contract (sometimes referred to as a "right to compete" clause);

(7) Is not easily readable (e.g., formatting and typeface) and is not labeled, in large letters, SERVICE CONTRACT; or

(8) Requires a Customer to give Defendants the right or opportunity to provide hauling service for recyclables or more than one solid waste hauling service for a Customer unless the

Customer affirmatively chooses to have Defendant do so by so stating on the front of the contract.

(B) Notwithstanding the provisions of paragraph IV(A) of this Final Judgment, Defendants may enter into a contract with a Customer for a service location in the Savannah or Central Louisiana markets with an initial term in excess of two years provided that:

(1) The Customer has acknowledged in writing that the Defendants have offered to the Customer the form contracts Defendants are required herein to offer generally to Customers;

(2) the Customer has the right to terminate the contract after 2 years by giving notice to Defendants thirty (30) days or more prior to the end of that 2 year period;

(3) the contract otherwise complies with the provisions of paragraph IV(A) (2)-(8); and

(4) the number of service locations subject to contracts permitted under subparagraph (B) in either the Savannah or Central Louisiana markets does not exceed 25% of the total number of service locations for small containerized solid waste hauling service in each such market in any year.

(C) From the date of filing of an executed Stipulation in the form attached hereto as Exhibit A, Defendants shall offer to new Customers with service locations in the Savannah and Central Louisiana markets only contracts that conform to the requirements of paragraphs IV (A) or (B) of this Final Judgment, except as provided in IV(G).

(D) Except as provided in IV(G), within thirty (30) days following the entry of this Final Judgment, Defendants shall send to all existing Customers with service locations in the Savannah and Central Louisiana markets with contracts having an initial term longer than 2 years and which otherwise do not conform with paragraph IV(B) a notice in the form attached hereto as Exhibit B.

(E) Except as provided in IV(G), for each Customer with a contract having an initial term longer than 2 years and which otherwise does not conform to paragraph IV(B) that enters a renewal term 120 days after entry of this Final Judgment, Defendants shall send a reminder to that Customer in the form attached hereto as Exhibit C ninety (90) days or more prior to the effective date of the renewal term. This reminder may be sent to the Customer as part of a monthly bill, but if it is, it must be displayed on a separate page and in large print.

(F) Upon entry of this Final Judgment, Defendants may not enforce those

contract provisions that are inconsistent with this Final Judgment.

(G) Notwithstanding the provisions of this Final Judgment, Defendants may enter into contracts with municipal or governmental entities that are not in compliance with paragraphs IV (A)–(F) provided that those contracts are awarded to Defendants on the basis of a formal request for bids or a formal request for proposals issued by the Customer.

(H) Notwithstanding the provisions of this Final Judgment, Defendants shall not be required to do business with any Customer.

#### V.

##### *Reporting*

(A) To determine or secure compliance with this Final Judgment, duly authorized representatives of the Plaintiff shall, upon written request of the Assistant Attorney General in charge of the Antitrust Division, on reasonable notice given to Defendants at their principal offices, subject to any lawful privilege, be permitted:

(1) Access during normal office hours to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other documents and records in the possession, custody, or control of Defendants, which may have counsel present, relating to any matters contained in this Final Judgment.

(2) Subject to the reasonable convenience of Defendants and without restraint or interference from them, to interview officers, employees, or agents of Defendants, who may have counsel present, regarding any matters contained in this Final Judgment.

(B) Upon written request of the Assistant Attorney General in charge of the Antitrust Division, on reasonable notice given to Defendants at their principal offices, subject to any lawful privilege, Defendants shall submit such written reports, under oath if requested, with respect to any matters contained in this Final Judgment.

(C) No information or documents obtained by the means provided by this Section shall be divulged by the Plaintiff to any person other than a duly authorized representative of the Executive Branch of the United States government, except in the course of legal proceedings to which the United States is a party, or for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

(D) If at the time information or documents are furnished by Defendants

to Plaintiff, Defendants represent and identify in writing the material in any such information or document to which a claim of protection may be asserted under Rule 26(c)(7) of the Federal Rules of Civil Procedure, and Defendants mark each pertinent page of such material "Subject to Claim of protection under Rule 26(c)(7) of the Federal Rules of Civil Procedure," then ten days notice shall be given by Plaintiff to Defendants prior to divulging such material in any legal proceeding (other than a grand jury proceeding) to which Defendants are not a party.

#### VI.

##### *Further Elements of Judgment*

(A) This Final Judgment shall expire on the tenth anniversary of the date of its entry.

(B) Jurisdiction is retained by this Court over this action and the parties thereto for the purpose of enabling any of the parties thereto to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify or terminate any of its provisions, to enforce compliance, and to punish violations of its provisions.

#### VII.

##### *Public Interest*

Entry of this Final Judgment is in the public interest.

Entered: \_\_\_\_\_  
United States District Judge

##### *Exhibit A*

United States District Court for the Southern District of Georgia, Savannah Division

In the matter of *United States of America, Plaintiff, v. Waste Management of Georgia, Inc., d/b/a Waste Management of Savannah, and Waste Management of Louisiana, Inc., d/b/a Waste Management of Central Louisiana, and Waste Management, Inc., Defendants.* Civil Action No.: CV496–35, filed: February 15, 1996.

##### *Stipulation*

It is stipulated by and between the undersigned parties, by their respective attorneys, that:

1. The Court has jurisdiction over the subject matter of this action and over each of the parties hereto for the purposes of this proceeding. Defendant Waste Management of Georgia, Inc., d/b/a Waste Management of Savannah, transacts business and is found within

the district. Defendants Waste Management of Louisiana, Inc., d/b/a Waste Management of Central Louisiana, and Waste Management, Inc. consent to personal jurisdiction in this proceeding. Defendants waive any objection as to venue and the parties stipulate that venue for this action is proper in the Southern District of Georgia;

2. The parties consent that a Final Judgment in the form hereto attached may be filed and entered by the Court, upon the motion of any party or upon the Court's own motion, at any time after compliance with the requirements of the Antitrust Procedures and Penalties Act (15 U.S.C. 16 (b)–(h)), and without further notice to any party or other proceedings, provided that Plaintiff has not withdrawn its consent, which it may do at any time before the entry of the proposed Final Judgment by serving notice thereof on the Defendants and by filing that notice with the Court; and

3. Defendants agree to be bound by the provisions of the proposed Final Judgment pending its approval by the Court. If the Plaintiff withdraws its consent or if the proposed Final Judgment is not entered pursuant to this Stipulation, this Stipulation shall be of no effect whatsoever, and the making of this Stipulation shall be without prejudice to any party in this or in any other proceeding.

Dated this \_\_\_\_th day of February, 1996.

Respectfully submitted,

For the Plaintiff the United States of America:

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Lawrence R. Fullerton,

*Deputy Assistant Attorney General.*

Rebecca P. Dick,

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Anthony V. Nanni,

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For the Defendants Waste Management, Inc., Waste Management of Georgia, Inc., and Waste Management of Louisiana, Inc.:

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Michael Sennett, Esquire,

*Bell, Boyd & Lloyd, 3 First National Plaza, 70 West Madison Street, Chicago, IL 60602.*

## Exhibit B

### Notice to Customers

Dear Valued Customer: [Insert name of local operating company] is offering a new two year contract to all small containerized solid waste hauling customers with service locations in [insert market here]. We would like to take this opportunity to offer this contract to you. Of course, if you prefer, you can continue with your existing contract.

In most cases, this new contract will have terms that are more advantageous to customers than their current contracts. This new contract has the following features:

- an initial term of 2 years (unless you request a longer term);
- a renewal term of 1 year;
- at the end of your initial term, you may take no action and your contract will renew or you can choose not to renew the contract by simply giving us notice at any time up to 30 days prior to the end of your term;
- 1 if you request a contract with a term longer than 2 years, you can cancel that contract after 2 years by giving us notice at any time up to 30 days prior to the end of the first 2 years;
- if you terminate the contract at any other time, you will be required to pay, as liquidated damages, no more than 3 times the greater of your prior monthly or average monthly charge. If you've been a customer continuously for more than 1 year, the liquidated damages would be reduced to 2 times the greater of your prior monthly or average monthly charge;
- you will not be required to give us notice of any offer from another waste hauling firm or to give us an opportunity to make a counteroffer although you may do so if you wish;
- you will be able to choose on the contract which specific types of waste hauling services you would like us to perform.

You may obtain a new contract containing these terms by calling [insert CSR telephone number or sales rep name and number].

If you prefer, you may continue with your existing contract. If you retain your existing contract, we will not enforce any terms that are inconsistent with the new form contract terms.

We thank you for your business and look forward to a continued relationship with you. If you have any questions, please call [WM contact person and phone number].

### Reminder to Customers

Your contract will automatically renew on MM/DD/YY unless we receive your cancellation by MM/DD/YY.

You may also obtain a new form contract with some terms more advantageous to you than your current contract.

You may obtain a new contract containing these terms by calling (insert CSR telephone number or sales rep name and number).

### United States District Court for the Southern District of Georgia Savannah Division

In the matter of *United States of America*, Plaintiff, v. *Waste Management of Georgia, Inc., d/b/a Waste Management of Savannah, Waste Management of Louisiana, Inc., d/b/a Waste Management of Central Louisiana, and Waste Management, Inc.*, Defendants. [Civil Action No.: CV496-35 Filed: February 15, 1996.]

### Competitive Impact Statement

The United States, pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act ("APPA"), 15 U.S.C. § 16 (b)-(h), files this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry in this civil proceeding.

#### I.

### *Nature and Purpose of the Proceeding*

On February 15, 1996, the United States filed a civil antitrust Complaint to prevent and restrain Waste Management, Inc. ("WMI"), Waste Management of Georgia, Inc. ("WMG"), d/b/a Waste Management of Savannah, and Waste Management of Louisiana, Inc. ("WML"), d/b/a Waste Management of Central Louisiana from using contracts that have restrictives and anticompetitive effects in the small containerized hauling service markets in Savannah and Central Louisiana, in violation of Section 2 of the Sherman Act, 15 U.S.C. As alleged in the Complaint, Defendants has attempted to monopolize small containerized hauling service in the Savannah and Central Louisiana geographic markets by using and enforcing contracts containing restrictive provisions to maintain and enhance their existing market power there.

The Complaint alleges that: (1) Defendant WMG has market power in small containerized hauling services in

the Savannah, GA market and Defendant WML has market power in small containerized hauling service in the Central Louisiana market; (2) Defendants, acting with specific intent, used and enforced contracts containing restrictives provisions to exclude and constrain competition and to maintain and enhance their market power in small containerized hauling service in those markets; (3) in the context of their large market shares and market power, Defendants' use and enforcement of those contracts in the Savannah and Central Louisiana markets has had anticompetitive and exclusionary effects by significantly increasing barriers to entry facing new entrants and barriers to expansion faced by small incumbents; (4) Defendants' market power is maintained and enhanced by their use and enforcement of those contracts; and, (5) as a result, there is a dangerous probability that Defendants will achieve monopoly power in the Savannah and Central Louisiana markets.

In its Complaint, Plaintiff seeks, among other relief, a permanent injunction preventing Defendants from continuing any of the anticompetitive practices alleged to violate the Sherman Act, and thus affording fair opportunities for other firms to compete in small containerized hauling service in the Savannah and Central Louisiana markets.

The United States and Defendants also have filed a stipulation by which the parties consented to the entry of a proposed Final Judgment designed to eliminate the anticompetitive effects of Defendants' actions in the Savannah and Central Louisiana markets. Under the proposed Final Judgment, as explained more fully below, in dealing with small-container customers in the Savannah and Central Louisiana markets, Defendants would only be permitted to enter into contracts containing significantly less restrictive terms than the contracts they now in use in those markets. Furthermore, Defendants would be prohibited from enforcing provisions in existing contracts that are inconsistent with the Final Judgment.

The United States and the Defendants have stipulated that the proposed Final Judgment may be entered after compliance with the APPA. Entry of the proposed Final Judgment would



terminate the action, except that the Court would retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and to punish violations thereof.

#### *Description of the Events Giving Rise to the Alleged Violation*

Waste Management, Inc. ("WMI"), a subsidiary of WMX Technologies, Inc., is the world's largest company engaged in the solid waste hauling and disposal business, with operations throughout the United States. WMI had total 1994 revenues of approximately \$5.8 billion.

Waste Management of Georgia, Inc. ("WMG"), d/b/a Waste Management of Savannah, is a subsidiary of WMI with its principal offices in Savannah, GA. It is the largest solid waste hauling and disposal company in the Savannah market. WMG had revenues of over \$14 million in its 1994 fiscal year.

Waste Management of Louisiana, Inc. ("WML"), d/b/a Waste Management of Central Louisiana, is also a subsidiary of WMI. It has offices in Alexandria, LA and Natchitoches, LA. It is the largest solid waste hauling and disposal company in the Central Louisiana market. WML had revenues over \$3 million in its 1994 fiscal year.

#### *A. The Solid Waste Hauling Industry*

Solid waste hauling involves the collection of paper, food, construction material and other solid waste from homes, businesses and industries, and the transporting of that waste to a landfill or other disposal site. These services may be provided by private haulers directly to residential, commercial and industrial customers, or indirectly through municipal contracts and franchises.

Service to commercial customers accounts for a large percentage of total hauling revenues. Commercial customers include restaurants, large apartment complexes, retail and wholesale stores, office buildings, and industrial parks. These customers typically generate a substantially larger volume of waste than do residential customers. Waste generated by commercial customers is generally placed in metal containers of two to ten cubic yards provided by their hauling company. In the markets at issue, two to ten cubic yard containers are called "small containers." Small containers are collected primarily by frontend load vehicles that lift the containers over the front of the truck by means of a hydraulic hoist and empty them into the storage section of the vehicle, where the waste is compacted. Service to commercial customers that use small

containers is called "small containerized hauling service."

Solid waste hauling firms also provide service to residential and industrial (or "roll-off") customers. Residential customers, typically households and small apartment complexes that generate small amounts of waste, use noncontainerized solid waste hauling service, normally placing their waste in plastic bags, trash cans, or small plastic containers at curbside.

Industrial or roll-off customers include factories and construction sites. These customers either generate non-compactible waste, such as concrete or building debris, or very large quantities of compactible waste. They deposit their waste into very large containers (usually 20 to 40 cubic yards) that are loaded onto a roll-off truck and transported individually to the disposal site where they are emptied before being returned to the customer's premises. Some customers, like shopping malls, use large, roll-off containers with compactors. This type of customer generally generates compactible trash similar to the waste of commercial customers, but in much greater quantities; it is more economical for this type of customer to use roll-off service with a compactor than to use a number of small containers picked up multiple times a week.

#### *B. Relevant Product Market*

The relevant product market is small containerized hauling service. There are no practical substitutes for this service. Small containerized hauling service customers will not generally switch to noncontainerized service in the event of a price increase, because it is too impractical and more costly for those customers to bag and carry their volume of trash to the curb for hand pick-up. Similarly, roll-off service is much too costly and the container takes up too much space for most small containerized hauling service customers. Only customers that generate the largest volumes of compactible solid waste can economically consider roll-off service, and for customers that do generate large volumes of waste, roll-off service is usually the only viable option.

#### *C. Relevant Geographic Markets*

The relevant geographic markets are the Savannah market and the Central Louisiana market. Small containerized solid waste hauling services are generally provided in very localized areas. Route density (a large number of customers that are close together) is necessary for small containerized solid waste hauling firms to be profitable. In addition, it is not economically efficient

for heavy trash hauling equipment to travel long distances from customers without collecting significant amounts of waste. Thus, it is not efficient for a hauler to serve major metropolitan areas from a distant base. Haulers, therefore, generally establish garages and related facilities within each major local area served.

#### *D. Defendants' Attempt to Monopolize*

Defendant WMG has market power in small containerized hauling service in the Savannah market. WMG has maintained a very high market share since at least 1991—consistently in excess of 60 percent.

Defendant WML has market power in small containerized hauling service in the Central Louisiana market. WML has maintained a very high market share since at least 1988—consistently in excess of 60 percent.

There are substantial barriers to entry and to expansion into the small containerized hauling markets in Savannah and in Central Louisiana. A new entrant or small incumbent hauler must be able to achieve minimum efficient scale to be competitive. First, it must be able to generate enough revenues to cover significant fixed costs and overhead.

Second, a new entrant or small incumbent hauler must be able to obtain enough customers to use its trucks efficiently. For example, it is not efficient to use a truck half a day because the firm doesn't have enough customers to fill up the truck.

Third, a new entrant or small incumbent hauler needs to obtain customers that are close together on its routes (called "route density"). Having customers close together enables a company to pick up more waste in less time (and generate more revenues in less time). The better a firm's route density, the lower its operating costs.

Until a firm overcomes these barriers, the new entrant or small incumbent will have higher operating costs than Defendants in the relevant geographic markets, may not operate at a profit, and will be unable effectively to constrain pricing by Defendants in those markets.

Defendant WMG in the Savannah market and Defendant WML in the Central Louisiana market have entered into written contracts with the vast majority of their small containerized hauling customers. Many of these contracts contain terms that, when taken together in the relevant markets where Defendants have market power, make it more difficult and costly for customers to switch to a competitor of Defendants and allows Defendants to bid to retain customers approached by a competitor.



The contracts enhance and maintain Defendants' market power in the Savannah and Central Louisiana markets by significantly raising the cost and time required by a new entrant or small incumbent firm to build its customer base and obtain efficient scale and route density. Therefore, Defendants' use and enforcement of these contracts in the Savannah and Central Louisiana markets raise barriers to entry and expansion in those markets. Those contract terms are:

a. A provision giving Defendants the exclusive right to collect and dispose of all the customers' solid waste and recyclables;

b. An initial term of three years;

c. A renewal term of three years that automatically renews unless the customer sends Defendants a written notice of cancellation by certified mail more than 60 days from the end of the initial or renewal term;

d. A term that requires a customer that terminates the contract at any other time to pay Defendants, as liquidated damages, its most recent monthly charge times six (if the remaining term is six or more months) or its most recent monthly charge times the number of months remaining under the contract (if the remaining term is less than six months); and

e. A "right to compete" clause that requires the customer to give Defendants notice of any offer by or to a hauling competitor or requires the customer to give Defendants a reasonable opportunity to respond to such an offer for any period not covered by the contract.

The appearance and format of the contracts also enhances Defendants' ability to use the contracts to maintain their market power in these markets. The provisions that make it difficult for a customer to switch to a competing hauler are not obvious to customers in the relevant markets. The document is not labeled "Contract" so its legally binding nature is not always apparent to the customer. Also, all the restrictive provisions mentioned above are in small print on the back of the document.

Defendants' use and enforcement of the contracts described above in the Savannah and Central Louisiana markets have raised the barriers already faced by new entrants and small existing firms in those markets. Defendants' use and enforcement of the contracts has reduced the likelihood that the customers will switch to a Defendant's competitor. Given Defendants' market power, this has made it more difficult for competitors to achieve efficient scale, obtain sufficient customers to use their trucks efficiently,

and develop sufficient route density to be profitable and to constrain Defendants' pricing in those markets.

### III

#### *Explanation of the Proposed Final Judgment*

The proposed Final Judgment will end the unlawful practices currently used by Defendants to perpetuate and enhance their market power in the Savannah and Central Louisiana markets. It requires Defendants to offer less restrictive contracts to small containerized hauling customers in the Savannah and Central Louisiana markets.<sup>1</sup>

In particular, Paragraphs IV (A) and (B) prohibit Defendants from entering into contracts containing the type of restrictive terms described above. Paragraphs IV(C), (D), (E), and (F) are designed to bring existing contracts into compliance with the proposed Final Judgment on an expeditious basis.

#### *A. Prohibition of Contract Terms and Formats*

The Contracts used most frequently by defendants in the relevant markets have an initial term of three years and renew automatically and perpetually for additional three-year terms unless cancelled by the customer. In these markets, given that the Defendants have market power and a vast majority of their existing customers are subject to such contracts, the long initial term and long renewal terms prevent new entrants and small incumbents, no matter how competitive, from quickly obtaining enough customers that are close together to be profitable. Shortening the initial term and the renewal term will allow competitors to compete for more of the customer base each year and, if they compete effectively, to obtain efficient scale and route density more quickly. This, in turn, will enhance competition in the relevant markets and will help offset Defendants' market power.

Paragraph IV(A)(1) prohibits Defendants from using contracts for service locations in the Savannah and Central Louisiana markets that have an initial term longer than two years,

<sup>1</sup> The proposed Final Judgment applies to all contracts entered into by Defendants with customers for service locations in the relevant markets except contracts described in Paragraph IV (G). Contracts awarded to Defendants by municipal or government entities as a result of a formal request for bids or a formal request for proposals need not contain the provisions dictated by the proposed Final Judgment. These contracts were excluded from the decree to assure that competition for such bids would not be adversely affected by preventing Defendants from bidding.

except under certain very limited circumstances.

A contract with an initial term in excess of two years in the relevant markets is permitted, under limited circumstances, pursuant to Paragraph IV(B) of the proposed Final Judgment, but the contracts must otherwise conform to the Final Judgment. The United States is aware that some customers, for valid business reasons such as long-term price assurance, want contracts with an initial term longer than two years. Paragraph IV(B) is intended to permit customers who want them to have such contracts, while ensuring that customers who have not made such a choice do not, nevertheless, find themselves with long contracts. Under Paragraph IV(B)(1), Defendants may sign a contract of longer than two years with a customer, but only if the customer has been offered the two year contract and has acknowledged, in writing, that this offer was made.<sup>2</sup> Even if the customer signs a contract with an initial term longer than two years, the customer retains the right to terminate that contract at the end of the first two years, without payment of any liquidated damages, pursuant to Paragraph IV(B)(2). Paragraph IV(B) was included to give Defendants the ability to contract with customers who truly want a longer term, for the United States anticipates that contracts with initial terms longer than two years will be the exception, not the rule. To assure such an outcome, Paragraph IV(B)(4) limits the number of service locations subject to such contracts in either the Savannah or Central Louisiana markets to no more than 25 percent of the total number of small containerized solid waste hauling service locations in each relevant market.

Paragraph IV(A)(2) prohibits Defendants from signing a contract with a renewal term longer than one year in length, down from the three-year renewal term used as a standard in the Savannah and Central Louisiana markets.

Paragraph IV(A)(3) increases the period of time that a customer may notify Defendants of its intention not to renew the contract from a period ending 60 days before the end of any initial or renewal term to a period ending 30 days before the end of any such term. This allows the customer to make a decision concerning renewal closer to the end of

<sup>2</sup> The United States envisions that the customer's written acknowledgment that the two year contract was offered, but declined, by the customer could be made by having the customer check an appropriate box on the face of the contract near the customer's signature, or by some similar mechanism.

the contract term. A customer is more likely to consider whether or not it wants its existing contract renewal the closer than customer is to the end of the contract term. Paragraph IV(A)(3) assures that a customer will be able to choose not to renew its contract up to 30 days from the end of the contract term. Paragraph IV(A)(3) also eliminates the requirement that a customer give its nonrenewal notice in writing and send it to Defendants by certified mail. A telephone call or letter is sufficient under the proposed Final Judgment. These changes in the notification provisions make it easier for the customer not to renew within the terms of the contract. This, in turn, enhances customer choice and enables a new entrant or small incumbent to compete for more customers.

A liquidated damages provision is intended to allow a seller to recover otherwise unrecoverable costs where the amount of the damage resulting from a breach of contract is difficult to determine. Defendants do incur some unrecoverable costs, including sales costs, in contracting with customers for small containerized solid waste hauling services. The contract currently most widely used by Defendants in the relevant markets contain the following liquidation damages provision for early termination: the customer must pay six times its prior monthly charge unless the contract has a remaining term of less than six months, in which case the customer pays its prior monthly charge times the number of months remaining in its contract term. If this case went to trial, the United States believes it could prove that these liquidated damages far surpass the contracting costs the Defendants incur, and that, in the relevant markets where Defendants have market power, Defendants have threatened to enforce such liquidated damages provisions with the effect that customers did not switch to new entrants and small incumbents when they desired to do so. In the presence of market power, the threat of enforcing large liquidated damages provisions can deter sufficient customers from switching to a competitor and harm competition.

Paragraphs IV(A) (4) and (5) reduce the amount of liquidated damages Defendants can collect from a customer. The liquidated damages Defendants may collect from a customer in the relevant markets during the first year of the initial term of a customer's contract are reduced to the greater of three times the customer's prior monthly charge or average monthly charge over the prior six months. A firm that has been a customer of a Defendant for a

continuous period in excess of one year can be required to pay Defendants no more than two times the greater of the customer's prior monthly charge or average monthly charges over the past six months. The changes made in the liquidated damages provisions make it less expensive (and therefore more likely) that a customer can switch to a competing hauler should it choose to do so during the contract term. Defendants have incurred costs to sign small containerized solid waste hauling customers to contracts. However, as customers pay their monthly bills over time, the unrecovered amount of those costs decreases. That fact is reflected in the proposal Final Judgment by the reduction of the liquidated damages Defendants may collect once a firm has been Defendants' customer for more than one year.

Paragraph IV(A)(6) prohibits Defendants from including a "right to compete" clause in their contracts in the relevant markets. That clause requires a customer to give Defendants notice of any offer by or to another solid waste hauling firm or requires the customer to give Defendants a reasonable opportunity to respond to such an offer for any period not covered by the contract. Defendants currently use a clause in the vast majority of contracts in use in the Savannah and Central Louisiana markets.<sup>3</sup> Such a clause enables a firm with market power easily to deny a sufficient customer base to new entrants or small incumbents because the customer must notify it of the terms of offers from competitors before the competitor obtains a single customer's business. It is a simple matter for the dominant firm to match or beat the competitor's price and induce the customer not to switch to the competitor. Furthermore, it allows the dominant firm to target price reductions only to those customers approached by a competitor without dropping prices across the board. The existence of this clause reduces a new entrant's expected profitability for luring a customer away from Defendants. It has the effect of retarding entry. The Final Judgment prohibits the use of this provision in the relevant markets.

The contracts predominantly used by Defendants in the relevant markets currently give Defendants the exclusive right to perform all of a customer's solid

waste hauling services and recycling, just because the customer has signed a contract for small containerized solid waste hauling service. Paragraph IV(A)(8) of the proposed Final Judgment prohibits this provision in the relevant markets. Instead, it provides that Defendants may perform only those services a customer selects. Defendants may perform all types of solid waste hauling services and recycling for a customer only if the customer affirmatively chooses to have Defendants do so by so stating on the front of the contract.<sup>4</sup> The United States does not intend this provision to prohibit Defendants from requiring that it be the exclusive supplier of any type of service for which it contracts with a customer. For example, if a customer contracts with Defendants to perform small containerized solid waste hauling service at a specific service location, Defendants may require that it be the exclusive supplier for that service at that location.

Paragraph IV(A)(7) of the proposed Final Judgment also requires Defendant to change the appearance and format of its contracts in the relevant markets. If this case went to trial, evidence from customers in those markets would show that some of them were not aware they had signed legally binding documents. Therefore, the proposed Final Judgment requires that the document be labeled "SERVICE CONTRACT" in large letters. Furthermore, evidence from customers in the relevant markets would show that the contractual provisions that enable a firm with market power to restrict customers from switching to a competitor are in very small print on the back of the document. The proposed Final Judgment requires that the contracts used in the relevant markets be easily readable in formatting and type-face.

#### *B. Transition Rules*

In the Stipulation consenting to the entry of the proposed Final Judgment, Defendants agreed to abide by the provisions of the proposed Final Judgment immediately upon the filing of the Complaint, *i.e.*, as of February 15, 1996. Among other things, the transition provisions described herein will require Defendants to abide by the foregoing limitations and prohibitions when entering into any contracts with new small containerized hauling customers after February 15, 1996. Certain additional provisions of the proposed

<sup>3</sup> The clause reads: "RIGHT TO COMPETE. Customer grants to Contractor the right to compete with any offer which Customer receives (or intends to make) relating to the provision of nonhazardous waste collection and disposal services upon the termination of this Agreement for any reason, and agrees to give Contractor written notice of any such offer and reasonable opportunity to respond to it."

<sup>4</sup> The United States anticipates that the customer should be able to affirmatively indicate its choice of service types by checking a box, by writing in the type of service it wants on the front of the contract, or by some similar mechanism.

Final Judgment also apply to existing customer contracts that are inconsistent with the proposed Final Judgment's requirements for new customer contracts.

Under Paragraph IV(C), Defendants must offer contracts that conform with Paragraphs IV(A) or (B) of the proposed Final Judgment to all new customers with service locations in the Savannah and Central Louisiana markets beginning today, the date of the filing of the executed Stipulation.

Under Paragraph IV(D), within 30 days of the entry of the proposed Final Judgment, Defendants must notify existing customers in the Savannah and Central Louisiana markets who have contracts with an initial term longer than two years and do not otherwise comply with the proposed Final Judgment of their right to sign a new contract complying with the proposed Final Judgment. These notices must also inform any customers choosing to retain their existing contracts that no provisions inconsistent with the proposed Final Judgment will be enforced against them. With regard to municipal and government entities, Defendants are not required to notify those entities with nonconforming contracts that were awarded on the basis of a formal request for bids or a formal request for proposals issued by the customer.

Paragraph IV(E) requires Defendants to give an additional notice in the form of a reminder to any customer subject to a nonconforming contract that enters a renewal term 120 days or more after the entry of the proposed Final Judgment. Defendants must send the reminder to each such customer ninety (90) days or more prior to the effective date of the renewal term. The reminder informs the customer that it must cancel its contract by a certain date or the contract will renew. It also reminds the customer that it may enter into a new contract conforming to the proposed Final Judgment on request and that terms in the customer's existing contract that are inconsistent with the new form will not be enforced against it. Defendants may send this reminder as part of a monthly bill, as long as it appears on a separate page and in large print so that it will be noticeable.

Under Paragraph IV(F), Defendants may not enforce contract provisions inconsistent with the Final Judgment upon entry of the Final Judgment by the Court.

Under Paragraphs IV (G) and (H), the proposed Final Judgment makes clear that contracts awarded by municipal or government entities on the basis of a formal request for bids or proposals

issued by the customer need not comply with Paragraphs IV (A)–(F). Moreover, nothing in the proposed Final Judgment requires Defendants to do business with any customer.

Paragraphs IV (C)–(F) further two consistent goals. Opportunities for competition in small containerized hauling service in the relevant markets will be fostered by a rapid end to the provisions that significantly raise entry barriers in the relevant markets. At the same time, the transition rules avoid creating any unnecessary disruption of the customers' trash hauling service that might result from voiding all nonconforming contracts. Existing customers are not required to terminate or amend their existing contracts with Defendants; the choice belongs to the customer. However, Defendants may not enforce against any customer any provision inconsistent with the proposed Final Judgment.

To ensure that existing customers learn of their rights under the proposed Final Judgment, Paragraphs IV (D) and (E) require Defendants to notify customers of their rights under the Final Judgment and remind them of their right to terminate their existing contract or to sign a new contract form.

#### C. Enforcement

Section V of the proposed Final Judgment establishes standards and procedures by which the Department of Justice may obtain access to documents and information from Defendants related to their compliance with the proposed Final Judgment.

#### D. Duration

Section VI of the proposed Final Judgment provides that the Final Judgment will expire on the tenth year after its entry. Jurisdiction will be retained by the Court to conduct further proceedings relating to the Final Judgment, as specified in Section VI.

#### IV

##### *Remedies Available to Potential Private Litigants*

Section 4 of the Clayton Act (15 U.S.C. 15) provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages the person has suffered, as well as costs and reasonable attorneys' fees. Entry of the proposed Final Judgment will neither impair nor assist the bringing of any private antitrust damage action. Under the provisions of Section 5(a) of the Clayton Act (15 U.S.C. 16(a)), the proposed Final Judgment has no *prima facie* effect in

any subsequent private lawsuit that may be brought against defendants.

#### V

##### *Procedures Available for Modification of the Proposed Final Judgment*

The United States and Defendants have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least 60 days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within sixty (60) days of the date of publication of this Competitive Impact Statement in the Federal Register. The United States will evaluate and respond to the comments. All comments will be given due consideration by the Department of Justice, which remains free to withdraw its consent to the proposed Judgment at any time prior to entry. The comments and the response of the United States will be filed with the Court and published in the Federal Register.

Written comments should be submitted to: Anthony V. Nanni, Chief, Litigation I Section, Antitrust Division, United States Department of Justice, 1401 H Street NW., Suite 4000, Washington, DC 20530.

The proposed Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

#### VI

##### *Alternatives to the Proposed Final Judgment*

The United States considered, as an alternative to the proposed Final Judgment, litigation against Defendants. The United States could have brought suit and sought preliminary and permanent injunctions against the use and enforcement of these contracts by Defendants in the relevant markets. The United States is satisfied, however, that the relief outlined in the proposed Final Judgment will eliminate Defendants' ability to use restrictive and anticompetitive contracts to maintain and enhance their market power in the relevant markets. The United States believes that these contracts will no

longer inhibit the ability of a new entrant to compete with the Defendants. The relief sought will allow new entry and expansion by existing firms in those markets.

## VII

### *Standard of Review Under the APPA for Proposed Final Judgment*

The APPA requires that proposed consent judgments in antitrust cases brought by the United States be subject to a sixty-day comment period, after which the court shall determine whether entry of the proposed Final Judgment "is in the public interest." In making that determination, the court may consider—

(1) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration or relief sought, anticipated effects of alternative remedies actually considered, and any other considerations bearing upon the adequacy of such judgment;

(2) the impact of entry of such judgment upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. 16(e). As the D.C. Circuit recently held this statute permits a court to consider, among other things, the relationship between the remedy secured and the specific allegations set forth in the government's complaint, whether the decree is sufficiently clear, whether enforcement mechanisms are sufficient, and whether the decree may positively harm third parties. See *United States v. Microsoft*, 56 F.3d 1448, 1462 (D.C. Cir. 1995). In conducting this inquiry, "the Court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process."<sup>5</sup> Rather, absent a showing of corrupt failure of the government to discharge its duty, the Court, in making its public interest finding, should . . . carefully consider the explanations of the government in the competitive impact

statement and its responses to comments in order to determine whether those explanations are reasonable under the circumstances.

*United States v. Mid-America Dairymen, Inc.*, 1977-1 Trade Cas. ¶ 61,508, at 71,980 (W.D. Mo. 1977).

The Court's inquiry, under the APPA, is whether the settlement is "within the reaches of the public interest."<sup>6</sup> The proposed Final Judgment enjoins the Defendants' continued use of overly restrictive contract terms and opens local markets to increased competition, thus effectively furthering the public interest.

## VIII.

### *Determinative Documents*

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Dated: February 15, 1996.

Respectfully submitted,

Nancy H. McMillen,

Peter H. Goldberg,

Evangelina Almirantearena,

*Attorneys, Antitrust Division, U.S.*

*Department of Justice, 1401 H Street NW., Suite 4000, Washington, D.C. 20530, (202) 307-5777.*

### *Certification of Service*

I hereby certify that a copy of the foregoing has been served upon Waste Management, Inc., Waste Management of Georgia, Inc., and Waste Management of Louisiana, Inc., by placing a copy of this Competitive Impact Statement in the U.S. mail, directed to each of the above-named parties at the addresses

given below, this 15th day of February, 1996.

Michael Sennett,

*Esquire, Bell, Boyd & Lloyd, 3 First National Plaza, 70 West Madison Street, Chicago, IL 60602.*

Robert E. Bloch,

*Esquire, Mayer, Brown & Platt, 2000 Pennsylvania Ave., N.W., Washington, D.C. 20003.*

Harold Hellin,

*Esquire,*

Glen Darbyshire,

*Esquire, Hunter, MacLean, Exler & Dunn, 200 East Street Julian, Savannah, GA 31401.*

Nancy H. McMillen,

*Attorney, U.S. Department of Justice, Antitrust Division, 1401 H Street, N.W., Suite 4000, Washington, D.C. 20530, (202) 307-5777.*

United States District Court for the Southern District of Georgia, Savannah Division

In the matter of *United States of America, Plaintiff, v. Waste Management of Georgia, Inc., d/b/a Waste Management of Savannah, Waste Management of Louisiana, Inc., d/b/a Waste Management of Central Louisiana, and Waste Management, Inc. Defendants*. [Civil Action No.: CV496-35] filed February 15, 1996.

Motion of United States to Exclude Case From All Discovery Requirements and To Follow the Procedures of the Antitrust Procedures and Penalties Act

The United States of America hereby moves the Court for an order to exclude this case from all discovery requirements under the Federal Rules of Civil Procedure and the Local Rules of the United States District Court for the Southern District of Georgia, given that the disposition of a negotiated civil antitrust case brought and settled by the United States is governed by the Antitrust Procedures and Penalties Act, 15 U.S.C. 16 (b)-(h) [hereinafter "the APPA"]. The United States further moves the Court for inclusion in this Order for an exemption from the requirement that Defendants file any responsive pleading to the Complaint.

As set forth below, the parties have consented to the entry of the proposed Final Judgment without trial or adjudication of any issue of fact or law, and without the Final Judgment constituting any evidence against or an admission by any party with respect to any such issue. Pursuant to the procedures of the APPA, discovery between the parties is unnecessary and would be contrary to the intentions of the parties. Therefore, the United States respectfully requests that the Court enter the attached Order which excludes the case from all discovery requirements

<sup>5</sup> 119 Cong. Rec. 24598 (1973). See *United States v. Gillette Co.*, 406 F. Supp. 713, 715 (D. Mass. 1975). A "public interest" determination can be made properly on the basis of the Competitive Impact Statement and Responses to Comments filed pursuant to the APPA. Although the APPA authorizes the use of additional procedures, 15 U.S.C. § 16(f), those procedures are discretionary. A court need not invoke any of them unless it believes that the comments have raised significant issues and that further proceedings would aid the court in resolving those issues. See H.R. Rep. 93-1463, 93rd Cong. 2d Sess. 8-9, reprinted in (1974) U.S. Code Cong. & Ad. News 6535, 6538.

<sup>6</sup> *United States v. Bechtel*, 648 F.2d 660, 666 (9th Cir.), cert. denied, 454 U.S. 1083 (1981); (citations omitted) (emphasis added); see *United States v. BNS, Inc.*, 858 F.2d 456, 463, (9th Cir. 1988); *United States v. National Broadcasting Co.*, 449 F. Supp. 1127, 1143 (C.D. Cal 1978); *United States v. Gillette Co.*, 406 F. Supp. at 716; see also *United States v. American Cyanamid Co.*, 719 F.2d 558, 565 (2d Cir. 1983), cert. denied, 465 U.S. 1101 (1984); *United States v. American Tel. and Tel. Co.*, 552 F. Supp. 131, 150 (D.D.C. 1982), *aff'd sub nom. Maryland v. United States*, 460 U.S. 1001 (1983) quoting *United States v. Gillette Co.*, supra, 406 F. Supp. at 716; *United States v. Alcan Aluminum, Ltd.*, 605 F. Supp. 619, 622 (W.D. Ky 1985).

of the Federal Rules of Civil Procedure and the Local Rules of the United States District Court for the Southern District of Georgia, and states that the disposition of the case will be consistent with the APPA.

1. On February 15, 1996, the United States filed a Complaint and a Stipulation by which the parties agreed to the Court's entry of an attached proposed Final Judgment following compliance with the APPA.

2. The United States also filed on February 15, 1996, a Competitive Impact Statement as required by 15 U.S.C. 16(b).

3. The APPA also requires the United States to publish a copy of the proposed Final Judgment and the Competitive Impact Statement in the Federal Register. It further requires the publication of summaries of the terms of the proposed Final Judgment and the Competitive Impact Statement in at least two newspapers of general circulation. This notice will inform members of the public that they may submit comments about the Final Judgment to the United States Department of Justice, Antitrust Division. 15 U.S.C. 16(b)-(c).

4. Following such publication in the newspapers and Federal Register, a sixty-day waiting period will begin. During this time, the United States will consider, and at the close of that period respond to, any public comments that it receives. It will publish the comments and its responses in the Federal Register. 15 U.S.C. 16(d).

5. After the expiration of the sixty-day period, the United States will file with the Court the comments, the Government's responses, and a Motion For Entry of the Final Judgment. 15 U.S.C. 16(d).

6. After the filing of the Motion For Entry of the Final Judgment, the Court may enter the Final Judgment without a hearing, if it finds that the Final Judgment is in the public interest. 15 U.S.C. 16(e)-(f).

7. The parties fully intend to comply with the requirements of the APPA.

As stated above, the Antitrust Procedures and penalties Act governs the disposition of civil antitrust cases brought and settled by the United States. Discovery between the parties, which have consented to the proposed settlement filed with the Court, is unnecessary. Accordingly, the attached Order is justified and should be entered by the Court.

Respectfully submitted,

Harry D. Dixon, Jr.,

*United States Attorney, Southern District of Georgia, 100 Bull Street, Suite 201, Savannah, GA 31401, Tel.: (912) 652-4422.*

Nancy H. McMillen,

*Trial Attorney, U.S. Department of Justice, Antitrust Division, 1401 H Street NW., Suite 4000, Washington, DC 20530, Tel.: (202) 307-5777.*

#### Certificate of Service

I hereby certify that on February 15, 1996, a true and correct copy of the foregoing has been served on the parties below by placing a copy of this MOTION OF UNITED STATES TO EXCLUDE CASE FROM ALL DISCOVERY REQUIREMENTS AND TO FOLLOW THE PROCEDURES OF THE ANTITRUST PROCEDURES AND PENALTIES ACT in the U.S. Mail, postage prepaid, to the addresses given below.

For Defendants Waste Management of Georgia, Inc., Waste Management of Louisiana, Inc., and Waste Management, Inc.:

Michael Sennett, Esquire, Bell, Boyd & Lloyd, 3 First National Plaza, 70 West Madison Street, Chicago, IL 60602

Robert Bloch, Esquire, Mayer, Brown & Platt, 2000 Pennsylvania Ave. NW., Washington, DC 20006

Harold Hellin, Esquire, Glen Darbyshire, Esquire, Hunter, MacLean, Exler & Dunn, 200 East Street Julian, Savannah, GA 31401.

Nancy H. McMillen,

*Trial Attorney, U.S. Department of Justice, Antitrust Division, 1401 H Street NW., Suite 4000, Washington, DC 20530, (202) 307-5777.*

United States District Court for the Southern District of Georgia Savannah Division

In the matter of *United States of America, Plaintiff, v. Waste Management of Georgia, Inc., d/b/a Waste Management of Savannah, Waste Management of Louisiana, Inc. d/b/a Waste Management of Central Louisiana, and Waste Management, Inc., Defendants.* Civil Action No.: CV496-35, filed: Feb. 15, 1996.

Order Excluding Case From All Discovery Requirements and To Follow the Procedures of the Antitrust Procedures and Penalties Act

Plaintiff, the United States of America, has moved the Court to exclude this case from all discovery requirements under the Federal Rules of Civil Procedure and the Local Rules of the United States District Court for the Southern District of Georgia, given that the disposition of negotiated civil antitrust consent decrees are governed by the Antitrust Procedures and Penalties Act, 15 U.S.C. 16 (b)-(h). The

Court is of the opinion that this motion should be granted.

It is therefore Ordered that this case is excluded from all discovery requirements under the Federal Rules of Civil Procedure and the Local Rules of the United States District Court for the Southern District of Georgia. It is further ORDERED that the Defendants are not required to file any responsive pleading to the Complaint.

It is also therefore Ordered that the procedures to be followed in this case shall be consistent with the Antitrust Procedures and Penalties Act, 15 U.S.C. 16 (b)-(h).

Dated: \_\_\_\_\_

United States District Judge.

[FR Doc. 96-5040 Filed 3-4-96; 8:45 am]

BILLING CODE 4410-01-M

#### Notice Pursuant to the National Cooperative Research and Production Act of 1993—IHDT Cooperative Agreement Program

Notice is hereby given that, on November 6, 1995, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. § 4301 *et seq.* ("the Act"), IHDT Cooperative Agreement Program, has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties and (2) the nature and objectives of the Program. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to Section 6(b) of the Act, the identities of the parties are: Bell Helicopter Textron Inc., Hurst, TX; and McDonnell Douglas Helicopter Systems, Mesa, AZ.

The nature and objectives of this Program are the development of integrated software and database architecture that will assist U.S. aerospace companies and civilian and military program managers to reduce cycle time and to improve product affordability in the design, manufacture, and maintenance of rotocraft.

Constance K. Robinson,

*Director of Operations, Antitrust Division.*

[FR Doc. 96-5038 Filed 3-4-96; 8:45 am]

BILLING CODE 4410-01-M

**Notice Pursuant to the National Cooperative Research and Production Act of 1993—Joint Research and Development Venture Agreement for Industrial Refrigeration**

Notice is given that, on July 14, 1995, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. § 4301 *et seq.* ("the Act"), Philip W. Winkler, Manager, Cryogenic Refrigerants & Systems of Air Products & Chemicals, Inc., has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties and (2) the nature and objectives of the venture agreement. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to Section 6(b) of the Act, the identities of the parties are Air Products & Chemicals, Inc., 7201 Hamilton Boulevard, Allentown, PA 18195-1501; and Lewis Energy Systems, Inc., 300 West 1100 North, North Salt Lake, UT 84054, and the general areas of their planned activity are to develop and demonstrate a new form of industrial refrigeration equipment using dry air as the working fluid in a closed cycle at high pressures; an award from the National Institute of Standards and Technology, U.S. Department of Commerce will partially fund this joint research and development activity.

Constance K. Robinson,  
*Director of Operations, Antitrust Division.*  
[FR Doc. 96-5039 Filed 3-4-96; 8:45 am]  
BILLING CODE 4410-01-M

**Notice Pursuant to the National Cooperative Research and Production Act of 1993—Petroleum Environmental Research Forum Project No. 94-14**

Notice is hereby given that, on February 9, 1996, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. § 4301, *et seq.* ("the Act"), the participants in the Petroleum Environmental Research Forum ("PERF") Project No. 94-14, titled "Cooperative Bioremediation Research Program," have filed written notifications simultaneously with the Attorney General and with the Federal Trade Commission disclosing (1) the identities of the parties to PERF Project No. 94-14 and (2) the nature and objectives of the research program to be performed in accordance with the Project. The notifications were filed for the purpose of invoking the Act's

provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to Section 6(b) of the Act, the identities of the current parties participating in PERF Project No. 94-14 are: Exxon Research & Engineering Company, Florham Park, NJ; Marathon Oil Company, Littleton, CO; Amoco Corporation, Chicago, IL; Texaco, Inc., Port Arthur, TX; Phillips Petroleum Company, Houston, TX; and RETEC, Inc., Pittsburgh, PA.

The nature and objective of the research program performed in accordance with PERF Project No. 94-14 is to provide planning and response guidelines for the use of solidifiers for upstream/downstream petroleum (on land) operations.

Participation in this project will remain open to interested persons and organizations until issuance of the final project report. The participants intend to file additional written notifications disclosing all changes in its membership.

Information about participating in PERF Project No. 94-14 may be obtained by contacting Mr. William Dahl, Exxon Research & Engineering Company, Florham Park, NJ.

Constance K. Robinson,  
*Director of Operations, Antitrust Division.*  
[FR Doc. 96-5037 Filed 3-4-96; 8:45 am]  
BILLING CODE 4410-01-M

**Drug Enforcement Administration**

[Docket No. 95-45]

**Gilbert Ross, M.D.; Revocation of Registration**

On May 24, 1995, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Gilbert Ross, M.D., (Respondent) of Great Neck, New York, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration, AR5677060, under 21 U.S.C. 824(a)(5), and deny any pending applications for renewal of such registration as a practitioner under 21 U.S.C. 823(f). Specifically, the Order to Show Cause alleged in substance that: (1) On November 19, 1992, the Respondent was indicated by a federal grand jury in the Southern District of New York on a 131-count indictment on charges of racketeering (RICO), mail fraud and money laundering arising from the operation of four sham medical clinics in upper Manhattan and the Bronx; (2) on November 10, 1993, after judgment

was entered against the Respondent, following a jury trial, on one count of racketeering (RICO) in violation of 18 U.S.C. 1962(d), one count of conspiracy in violation of 18 U.S.C. 1962(c), ten counts of mail fraud in violation of 18 U.S.C. 1341 and 1342, and one count of money laundering in violation of 18 U.S.C. 982 (a)(1) and (b)(1)(A), he was sentenced to 46 months incarceration followed by three years of supervised release and ordered to make restitution to the State of New York in the amount of \$612,855.00; and (3) on June 10, 1994, the Respondent was notified by the Department of Health and Human Services of his ten-year mandatory exclusion from participation in the Medicare/Medicaid program pursuant to 42 U.S.C. 1320a-7(a), as a result of the above-referenced conviction.

On June 26, 1995, the Respondent, through counsel, filed a timely request for a hearing, and the matter was docketed before Administrative Law Judge Mary Ellen Bittner. On July 28, 1995, Counsel for the Government filed a Motion to Amend Order to Show Cause and for Summary Disposition, alleging, additionally, that on or about July 20, 1995, DEA received notice from the Administrative Review Board for Professional Medical Conduct of the Department of Health for the State of New York (Medical Board), that the Respondent's license to practice medicine in New York had been revoked effective July 24, 1995. The motion was supported by a copy of the Medical Board's Decision and Order.

On August 10, 1995, the Respondent filed a request for an adjournment of this matter, asserting that judicial review of the Medical Board's decision was pending before a State court. Judge Bittner denied that request on August 11, 1995. The Respondent did not subsequently file a response to the Government's Motion for Summary Disposition. Further, the Respondent did not deny that his State license had been revoked.

On August 24, 1995, Judge Bittner issued her Opinion and Recommended Decision, Conclusions of Law and Recommended Ruling, in which she (1) found that the Respondent lacked authorization to practice medicine in New York; (2) found that the Respondent therefore lacked authorization to handle controlled substances in New York; (3) granted the Government's Motion for Summary Disposition, and (4) recommended that the Respondent's DEA Certificate of Registration be revoked. Neither party filed exceptions to her decision, and on September 25, 1995, Judge Bittner transmitted her opinion and the record

of these proceedings to the Deputy Administrator.

The Deputy Administrator has considered the record in its entirety, and pursuant to 21 CFR 1316.67, hereby issues his final order based upon findings of fact and conclusions of law as hereinafter set forth. The Deputy Administrator adopts, in full, the decision of the Administrative Law Judge. The Drug Enforcement Administration cannot register or maintain the registration of a practitioner who is not duly authorized to handle controlled substances in the State in which he conducts his business. 21 U.S.C. 802(21), 832(f), and 824(a)(3). This prerequisite has been consistently upheld. See *Dominick A. Ricci, M.D.*, 58 FR 51104 (1993); *James H. Nickens, M.D.*, 57 FR 59847 (1992); *Roy E. Hardman, M.D.*, 57 FR 49195 (1992); *Myong S. Yi, M.D.*, 54 FR 30618 (1989); *Bobby Watts, M.D.*, 53 FR 11919 (1988).

Judge Bittner also properly granted the Government's motion for summary disposition. Here, the parties did not dispute that the Respondent was unauthorized to practice medicine and to handle controlled substances in New York, the State in which he maintains his DEA Certificate of Registration. Although the Respondent disagreed with the action of the Medical Board, he presented no evidence to contradict the fact that he is currently without authorization to handle controlled substances. Therefore, it is well-settled that when no question of fact is involved, a plenary, adversary administrative proceeding involving evidence and cross-examination of witnesses is not obligatory. See *Dominick A. Ricci, M.D.*, 58 FR at 51104 (finding it "well settled that where there is no material question of fact involved, a plenary, adversarial administrative hearing [was] not required. Congress did not intend administrative agencies to perform meaningless tasks."); see also *Phillip E. Kirk, M.D.*, 48 FR 32887 (1983), *aff'd sub nom Kirk v. Mullen*, 749 F.2d 297 (6th Cir. 1984); *Alfred Tennyson Smurthwaite, M.D.*, 43 FR 11873 (1978); *NLRB v. International Association of Bridge, Structural and Ornamental Ironworkers, AFL-CIO*, 549 F.2d 634 (9th Cir. 1977).

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824, and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration AR5677060, previously issued to Gilbert Ross, M.D., be, and it hereby is, revoked, and that any pending applications for renewal of such registration be, and they hereby

are, denied. This order is effective April 4, 1996.

Dated: February 28, 1996.  
Stephen H. Greene,  
Deputy Administrator.  
[FR Doc. 96-5006 Filed 3-4-96; 8:45 am]  
BILLING CODE 4410-09-M

## DEPARTMENT OF LABOR

### Employment and Training Administration

#### Proposed Information Collection Request Submitted for Public Comment and Recommendations; Employment Service Reporting System

**ACTION:** Notice.

**SUMMARY:** The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)).

The Employment Service Program Reporting System provides data on State public employment service agency program activities and expenditures, including services to veterans, for use at the Federal level by the U.S. Employment Service and the Veterans Employment and Training Service in program administration and provides reports to the President and Congress. Currently, the Employment and Training Administration is soliciting comments concerning the proposed revision of information collection for the Employment Service Reporting System, on Form ETA 9002 A-C, ETA Quarterly Report; Form VET 200 A & B, VETS 200 DVOP/LVER Quarterly Report; Form VETS 300, VETS 300 Cost Accounting Report; and the Manager's Report on Services to Veterans.

Proposed revisions are: (1) To delete the line item reporting Non-Personal Service and Administrative Overhead on the VETS 300 Cost Accounting Report—minimal burden reduction; and (2) to reduce burden hours by eliminating the need for reprogramming of information on the SMOCTA program; and (3) to incorporate the approved burden hours for the Manager's Report on Services to Veterans.

A copy of the proposed information collection request can be obtained by contracting the employee listed below in the contact section of this notice.

**DATES:** Written comments must be submitted on or before May 6, 1996. Written comments should evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; enhance the quality, utility, and clarity of the information to be collected; and minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

**ADDRESSES:** Pearl Wah, U.S. Employment Service, Employment and Training Administration, Department of Labor, Room N-4470, 200 Constitution Avenue, N.W., Washington, D.C. 20210, 202-219-5185 (This is not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Information on basic labor exchange services is necessary to assure that States are complying with legal requirements of the Wagner-Peyser Act as amended by the Job Training Partnership Act (JTPA). Program data items are required from States reporting to the Department of Labor as part of other information in order to determine if States are complying with the basic labor exchange requirements.

Information regarding employment and training services provided to veterans by State public employment service agencies must be collected by the Department of Labor to satisfy legislative requirements, as follows: (a) To report annually to Congress on specific services (38 U.S.C. 2007(c) and 2012(c)); (b) to establish administrative controls (38 U.S.C. 2007(b)); and (c) for administrative purposes.

##### II. Current Actions

This is a request for OMB approval under the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A) to revise the collection of information previously approved and assigned OMB Control No. 1205-0240. This package will incorporate the burden activity and hours previously approved and assigned OMB Control No. 1293-0007 for the Manager's Report on Services to Veterans.



*Type of Review:* Revision.  
*Agency:* Employment and Training Administration.

*Titles:* Employment Service Program Reporting System.  
*Form Numbers:* ETA 9002 Quarterly Report; VETS 200 LVER Quarterly

Report; and VETS 300 Cost Accounting Report.  
*Agency Number:* 1205-1240.  
*Estimated Burden Hours:* 8249.

Reports	Respondents	Frequency	Responses	Avg. time per response	Burden
USES Rpt. ....	54	4	216	2.75	594
VETS Rpt. ....	54	4	216	.25	54
USES Rec. ....	54	1	54	12.00	648
VETS 200A ....	54	4	216	.75	162
VETS 200B ....	54	4	216	.75	162
VETS 300 ....	54	4	216	1.00	216
Mgt. Rpt. ....	1,600	4	6,400	.83	5,333
Totals .....	.....	.....	7,534	.....	8,249

Comments submitted in response to this notice will be summarized and/or included in the request for Office Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: February 23, 1996.

John M. Robinson,  
*Deputy Assistant Secretary, Employment Training Administration.*

[FR Doc. 96-5047 Filed 3-4-96; 8:45 am]

BILLING CODE 4510-30-M

## Office of Federal Contract Compliance Programs

### Rampart Electric, Inc., Debarment

**AGENCY:** Office of Federal Contract Compliance Programs, Labor.

**ACTION:** Notice of debarment, Rampart Electric, Inc.

**SUMMARY:** This notice advises of the debarment of Rampart Electric, Inc. (hereafter "Rampart"), as an eligible bidder on Government contracts and subcontracts and federally assisted construction contracts and subcontracts. The debarment is effective immediately.

**FOR FURTHER INFORMATION CONTACT:** Annie Blackwell, Director Program Policy, Office of Federal Contract Compliance Programs, U.S. Department of Labor, 200 Constitution Ave., NW, Room C-3325, Washington, DC. 20210 (202-219-9430).

**SUPPLEMENTARY INFORMATION:** On September 11, 1995, pursuant to 41 CFR 60-30.30, the Secretary of Labor issued a Final Decision and Order of Debarment and Related Sanctions: (1) Finding Rampart in violation of Executive Order 11246, as amended, and its implementing regulations; (2) cancelling all Federal contracts and subcontracts and all federally assisted construction contracts and subcontracts of Rampart, and of its officers,

(including Jeff Dwyer a/k/a Jeff Droyer and Jeff Dryer), agents, servants, employees, direct or beneficial owners, divisions or subsidiaries, and of those persons in active concert or participation with them who receive actual notice of the order by personal service or otherwise; declaring Rampart ineligible for extensions or other modifications of any existing Government contracts or subcontracts; and declaring Rampart and its successors, officers, agents, servants, employees, direct or beneficial owners, divisions or subsidiaries, and those persons in active concert or participation with them who receive actual notice of the order by personal service or otherwise, ineligible for the award of any Government contracts or subcontracts until Rampart satisfies the Deputy Assistant Secretary for Federal Contract Compliance Programs that is in compliance with Executive Order 11246, as amended. A copy of the Decision and Order is attached.

Signed October 26, 1995, Washington, DC.  
 Shirley J. Wilcher,

*Deputy Assistant Secretary For Federal Contract Compliance Programs.*

U.S. Department of Labor  
*Secretary of Labor, Washington, DC*

Date: September 11, 1995  
 Case No. 89-OFC-14.

In the Matter of *Office of Federal Contract Compliance Programs, United States Department of Labor*, Plaintiff v. *Rampart Electric, Inc.*, Defendant.

Before: The Secretary of Labor

### Final Decision and Order of Debarment and Related Sanctions

This proceeding arises under Executive Order No. 11,246, 3 CFR 339 (1964-65), *reprinted as amended* in 42 U.S.C. 2000e note (1988). Upon the Defendant's failure to respond and participate in these proceedings, the Administrative Law Judge (ALJ) issued

a [Recommended] Decision and Order (R.D. and O.), holding that the Defendant had thereby admitted the material allegations of fact in Plaintiff Office of Federal Contract Compliance's (OFCCP's) Administrative Complaint and had waived its right to a hearing. The ALJ recommended cancellation, termination, and suspension of existing Government contracts<sup>1</sup> and federally assisted construction contracts, and prohibition against extensions or other modifications of current contracts. R.D. and O. at 3.

After referring to the Defendant's failures to respond to the ALJ's Notice of Docketing and the Show Cause Order directing the Defendant to show why its failure to file either an answer to OFCCP's complaint or to the Notice of Docketing should not constitute an admission of OFCCP's allegations under 41 CFR 60-30.6, the ALJ held the following:

Defendants [sic] persistent refusal to pursue this matter has left this forum no alternative other than to find that it has ADMITTED all the material allegations of fact contained in the complaint and has hereby WAIVED its right to a hearing on this matter. Accordingly it is FOUND that:

1. Defendant Rampart Electric, Inc., at all times material hereto, has been a corporation engaged in construction, and has maintained corporate offices at 6605 Alberta Drive, Colorado Springs, Colorado 80918.

2. Defendant, at all times material hereto, has had a contract with the Army and Air Force Exchange Service as the subcontractor in an expansion project in Colorado Springs, Colorado, the value of which was in excess of \$10,000. Defendant was therefore a Government contractor within the meaning

<sup>1</sup> Contracts also connote subcontracts. See 41 CFR 60-1.3 (1995) (definitions of contract, contractor, federally assisted construction contract, government contract, prime contractor, subcontract, subcontractor); 41 CFR 60-4.1.



of Executive Order (E.O.) 11246, and was subject to the contractual obligations imposed on Government Contractors by E.O. 11246, and the implementing regulations, including the regulations found at 41 CFR Part 60-4 (affirmative action requirements for construction contractors and subcontractors).

3. A compliance review under E.O. 11246 was conducted. On June 21, 1987, plaintiff notified defendant of the problem areas which were identified in the compliance review. \* \* \*

4. On July 17, 1987, defendant entered into a Conciliation Agreement with OFCCP, committing defendant to submit Monthly Manpower Utilization Reports (Standard Form CC-257) to OFCCP. \* \* \*

5. Defendant failed to submit the required Monthly Manpower Utilization Reports (Standard Form CC-257), as provided for in the Conciliation Agreement.

6. OFCCP unsuccessfully attempted to secure the reports and defendant's compliance through means of conciliation and persuasion.

7. On January 28, 1989, OFCCP sent defendant a notice to show cause pursuant to 41 CFR 60-4.8 to which defendant failed to respond with (sic) 15 days. \* \* \*

8. Defendant continues to refuse to submit the reports which were due and is in violation of E.O. 11246, the implementing regulations and its Conciliation Agreement. R.D. and O. at 1-2.

Although the Defendant's failure to file an answer constituted an admission of OFCCP's complaint allegations, 41 CFR 60-30.6(b), a waiver of hearing and a lawful basis for the ALJ's subsequent adoption of OFCCP's material facts as alleged in its complaint, 412 CFR 60-30.6(c), the Defendant was further provided "an opportunity to file exceptions to (the R.D. and O.) and to file briefs in support of the exceptions." 41 CFR 60-30.6(c). The Defendant made no such filings with the Secretary.

The Office of Administrative Appeals (OAA) subsequently issued an Order to Ensure Service and Establish Briefing Schedule in response to Plaintiff's Motion for Entry of Default Judgment and Entry of Sanctions. Defendant did not reply to OAA's order and the document was returned with a notation (without attribution) that the Defendant had moved.<sup>2</sup>

<sup>2</sup> Review of the various documents in the record reveals that the name of Rampart Electric's President, Jeff Dwyer, has been spelled three different ways. The Conciliation Agreement is signed by "Joni Dwyer for" the typed name "Jeff Dwyer." The certificates of service in the Administrative Complaint, the Notice of Docketing and the Order to Show Cause refer to him as "Jeff Dwyer." The certificates of service in the Motion for Judgment on the Pleadings and the R.D. and O. list him as "Jeff Dwyer." The certificate of service in Plaintiff's Motion for Entry of Default Judgment and Entry of Sanctions and OAA's Order to Ensure Service and Establish Briefing Schedule refer to "Jeff Dwyer." All documents refer to him as President of Rampart Electric at 6605 Alberta Drive, Colorado Springs, Colorado. Subsequent inquiries,

I agree with the R.D. and O. and OFCCP's motion for entry of a default judgment and sanctions. Accordingly, I enter this default judgment and order sanctions, including debarment, for the Defendant's breach of its Conciliation Agreement to submit Monthly Manpower Utilization Reports necessary to measure compliance thereunder; its failure to respond to OFCCP's attempts to secure these reports through conciliation and persuasion and to respond to OFCCP's notice of violations; and its repeated failures to participate in the ALJ proceeding. Debarment and other procurement-related sanctions are authorized for both substantive and procedural violations of the Executive Order and implementing regulations. *Uniroyal, Inc. v. Marshall*, 482 F. Supp. 364, 371-75 (D.D.C. 1979); *OFCCP v. Milwaukee Fence Co.*, Case No. 91-OFC-3, Sec. Dec. and Fin. Admin. Ord., Oct. 6, 1992, slip op. at 1-4; *OFCCP v. Disposable Safety Wear Inc.*, Case No. 92-OFC-11, Sec. Dec. and Fin. Admin. Ord., Sept. 29, 1992, slip op. at 1-6, 13. Accordingly, I make the following ORDER:

1. All federal contracts and subcontracts and federally assisted construction contracts and subcontracts of Defendant, Rampart Electric, Inc., its successors, officers, agents, servants, employees, direct or beneficial owners, divisions or subsidiaries and those persons acting in concern with them shall be canceled, terminated and suspended; and

2. Defendant, Rampart Electric, Inc., its successors, officers, agents, servants, employees, direct or beneficial owners, divisions or subsidiaries and those persons in active concert or participation with them shall be ineligible for the award of new federal contracts and subcontracts or federally assisted construction contracts or subcontracts or the extension or modification of any such existing contracts or subcontracts.

These sanctions shall be implemented and shall remain in effect until such time as Defendant, Rampart Electric, Inc., its officers, agents,<sup>3</sup> servants, employees, direct or beneficial owners, divisions or subsidiaries, successors or assigns, and those persons in active concert or participation with them have satisfied the OFCCP Director, pursuant to 41 CFR 60-1.31, that Defendant is in compliance with the provisions of

including communications with the Colorado Secretary of State, have been unable to locate Mr. Dwyer and/or Rampart Electric.

<sup>3</sup> "Officers" and "agents" in this Order include Jeff Dwyer, a/k/a Jeff Dwyer and Jeff Dwyer in various portions of the record.

Executive Order No. 11,246, as amended, and the rules and regulations issued thereunder.

So Ordered.

Washington, DC.  
Robert B. Reich,  
Secretary of Labor.

#### Certificate of Service

Case Name: *OFCCP, USDOL v. Rampart Electric, Inc.*

Case No: 89-OFC-14.

Document: Final Decision and Order of Debarment and Related Sanctions.

A copy of the above-referenced document was sent to the following persons on September 11, 1995.

Kathleen Gorham,

#### Certified Mail

Jeff Dwyer, President, (a/k/a/ Jeff Dwyer, Jeff Dryer), Rampart Electric, Inc., 6605 Alberta Drive, Colorado Springs, CO 80910

Corporation Section, Colorado Secretary of State, 1560 Broadway, Suite, 200, Denver, CO 80202

Business Regulation Unit, Colorado Attorney General, 1525 Sherman Street, 5th Fl., Denver, CO 80203

Legal Services Unit (Public Contracts), Colorado Attorney General, 1525 Sherman Street, 5th Fl., Denver, CO 80203

Tedrick A. Housh, Jr., Regional Solicitor/USDOL, 1585 Federal Bldg., 1961 Stout Street, Denver, CO 80294, Attn: Henry C. Mahlman, S. Lorrie Ray

#### Hand Delivered

James Henry, Associate Solicitor, Civil Rights Division/SOL, U.S. Department of Labor, Room N-2464, 200 Constitution Avenue, NW., Washington, DC 20210

Heidi Finger, Esq., Willie Alexander, Esq., Civil Rights Division/SOL, U.S. Department of Labor, Room N-2464, 200 Constitution Avenue, NW., Washington, DC 20210

Diane A. Heim, Esq., Heather A. Joys, Esq., Civil Rights Division/SOL, U.S. Department of Labor, Room N-2464, Washington, DC 20210

#### Regular Mail

Hon. John M. Vittone, Acting Chief Administrative Law Judge, Office of Administrative Law Judge, 800 K Street, Suite 400, Washington, DC 20001-8002

[FR Doc. 96-5048 Filed 3-4-96; 8:45 am]

BILLING CODE 4510-27-M

## Occupational Safety and Health Administration

### Washington State Standards; Notice of Approval

1. *Background.* Part 1953 of Title 29, Code of Federal Regulations prescribes procedures under Section 18 of the Occupational Safety and Health Act of 1970 (hereinafter called the Act) by which the Regional Administrator for

Occupational Safety and Health (hereinafter called Regional Administrator) under a delegation of authority from the Assistant Secretary of Labor for Occupational Safety and Health (hereinafter called the Assistant Secretary) (29 CFR 1953.4) will review and approve standards promulgated pursuant to a State plan which has been approved in accordance with Section 18(c) of the Act and 29 CFR Part 1902. On January 26, 1973, notice was published in the Federal Register (38 FR 2421) of the approval of the Washington plan and the adoption of Subpart F to Part 1952 containing the decision.

The Washington plan provides for the adoption of State standards that are at least as effective as comparable Federal standards promulgated under Section 6 of the Act. Section 1953.20 provides that where any alteration in the Federal program could have an adverse impact on the at least as effective as status of the State program, a program change supplement to a State plan shall be required.

In response to Federal standard changes and on its own initiative the State submitted by letter dated August 19, 1994, from Mark O. Brown, Director, to James W. Lake, Regional Administrator, a State standard corrective housekeeping amendment comparable to 29 CFR 1910.1017, Vinyl Chloride, as published in the Federal Register (58 FR 35310) on June 30, 1993. The State's original Vinyl Chloride standard was approved in the Federal Register on August 17, 1976 (FR 35896). The change was adopted in Washington Administrative Order 94-07 on July 20, 1994, effective September 20, 1994. In addition, on its own initiative, the State submitted by letter dated February 8, 1991, from Joseph A. Dear, Director, to James W. Lake, Regional Administrator, and incorporated as part of the plan, a State standard amendment. The amendment added clarifying language on end-of-service-life indicators on respirator canisters or cartridges for vinyl chloride. The State standard is comparable to 29 CFR 1910.1017, Vinyl Chloride. The change was adopted in Administrative Order 90-18 on January 10, 1991 and effective February 12, 1991. Also, on its own initiative, the State submitted by letter dated September 26, 1986, from G. David Hutchins, Assistant Director, to James W. Lake, Regional Administrator, and incorporated as part of the plan, a State standard amendment. The amendment eliminated obsolete language and updated types of respirators to be used by employees exposed to vinyl chloride. The State standard is comparable to 29

CFR 1910.1017, Vinyl Chloride. The change was adopted in Administrative Order 86-28 on July 25, 1986 and effective August 25, 1986.

In response to Federal standard changes the State submitted by letter dated October 14, 1994, from Mark O. Brown, Director, to James W. Lake, Regional Administrator, and incorporated as part of the state plan, a State standard amendment. The amendment added clarifying language and made minor housekeeping changes comparable to 29 CFR 1910.132, Personal Protective Equipment, General Provisions, 29 CFR 1910.133, Eye and Face Protection, 29 CFR 1910.136, Foot Protection, 29 CFR 1910.138, Hand Protection, Appendix A to Subpart I, References for further Information (Non-mandatory) and Appendix B to Subpart I, Non-mandatory Compliance Guidelines for Hazard Assessment and Personal Protective Equipment Selection, as published in the Federal Register (59 FR 16360) on April 6, 1994 and corrections as published in the Federal Register (59 FR 33910) on July 1, 1994. The changes were adopted in Administrative Order 94-16 on September 30, 1994, effective November 20, 1994.

In response to Federal standard changes and on its own initiative the State submitted letters from the Director of Washington Department of Labor and Industries to James W. Lake, Regional Administrator, State standard amendments comparable to 29 CFR 1910.120 and 1926.65, Hazardous Waste Operations and Emergency Response. The Federal-initiated amendments and corrections were published in the Federal Register on March 6, 1989, final rule (54 FR 429317); April 13, 1990, corrections (55 FR 14072); April 18, 1991, corrections (56 FR 16832); and August 22, 1994, amended, (59 FR 40964). The only significant difference is that the State requires eighty hours of training for workers in certain site zones. The changes and amendments were adopted in: Administrative Order 89-10, October 10, 1989, effective November 24, 1989; Administrative Order 90-01, April 10, 1990, effective May 25, 1990; Administrative Order 90-14, October 1, 1990, effective November 15, 1990; Administrative Order 91-01, May 20, 1991, effective June 20, 1991; Administrative Order 91-07, November 22, 1991, effective December 24, 1991; Administrative Order 93-04, September 22, 1993, effective November 1, 1993; Administrative Order 94-07, July 20, 1994, effective September 20, 1994; Administrative Order 94-08, August 3, 1994, effective September 12, 1994 and

Administrative Order 94-22, January 18, 1995, effective March 10, 1995.

In response to Federal standard changes, the State submitted by letters from Richard A. Davis and Joseph A. Dear, Directors, to James W. Lake, Regional Administrator, a State standard amendment comparable to the Federal standard amendment, 29 CFR 1910.401(a)(2)(iv), and the definition for Scientific Diving in 1910.402, Commercial Diving Operations, as published in the Federal Register (47 FR 53365) on November 26, 1982. In addition, in the same letters, the State, on its own initiative, submitted amendments to WAC 296-37-510 through 590, Safety Standards for Commercial Diving Operations. The code was originally approved in the Federal Register (46 FR 50445) on October 13, 1981. The State's first submission was adopted December 26, 1986, effective January 25, 1987, under Administrative Order 86-44. National Office review revealed discrepancies and the submission was returned to the State for correction. On November 18, 1992, the State submitted a corrective amendment which incorporated all of the Federal amendments and State-initiated changes to date. The minor differences in the standard are: The State included requirements for air compressors and alarms; the State included a requirement for a safety line; the State uses the word recompression rather than decompression; and the State added a reference to its recordkeeping standards. The State has also submitted by letter dated August 19, 1994, from Mark O. Brown, Director, to James W. Lake, Regional Administrator, a State corrective amendment identical to the Federal amendment at 29 CFR 1910.401(a)(2)(iii), Commercial Diving, published in the Federal Register (58 FR 35310) on June 30, 1993. The State amendment was adopted on July 20, 1994, effective September 20, 1994, under Administrative Order 94-07.

In response to Federal standards changes, the State submitted by letter dated April 24, 1990, from Joseph A. Dear, Director, to James W. Lake, Regional Administrator, a State standard amendment comparable to 29 CFR 1910.66, Powered Platforms for Building Maintenance, as published in the Federal Register (54 FR 31408) on July 28, 1989. On February 8, 1991, the State submitted additional changes to its standard to make it identical to the OSHA standard in four places. On December 20, 1991, the State made a minor change to a reference to another part of its standard. Upon review of the State standard, it was determined to be

less effective than the OSHA standard, and on November 18, 1993, the State was asked to make corrections. On August 19, 1994, the State submitted the necessary minor corrections. The State's standard replaces, in its entirety, the original State standard, WAC 296-24-87, Powered Platforms for Exterior Building Maintenance, which received Federal approval (41 FR 34836) on August 17, 1976. The State standard, which is substantially identical to the Federal standard, is contained in WAC 296-24-870. It was adopted on April 10, 1990, effective April 25, 1990 under Administrative Order 84-18. The minor changes asked for by OSHA in its November 18, 1993 letter were adopted in Administrative Order 94-07 on July 20, 1994, effective September 20, 1994. The change made in the February 8, 1991 letter was adopted in Administrative Order 90-18, on January 10, 1991, effective February 12, 1991, and the change made in the December 20, 1991 letter was adopted in Administrative Order 91-07 on November 22, 1991, effective December 24, 1991.

On its own initiative, the State of Washington has submitted by letter dated September 5, 1990, from Joseph A. Dear, Director, to James W. Lake, Regional Administrator, a repeal of WAC 296-155-580 and adoption of WAC 296-155-48531, comparable to 29 CFR 1926.556, Aerial Lifts. The repeal and adoption occurred in Administrative Order 86-14, on January 21, 1986, effective February 20, 1986. Under Administrative Order 90-10, which was adopted on August 13, 1990, effective September 24, 1990, minor housekeeping changes were made. National Office review revealed discrepancies and the submission was returned to the State for correction. On September 8, 1992, the State submitted a corrective amendment that made the necessary changes. This submission was adopted on August 10, 1992, effective September 10, 1992, under Administrative Order 92-06. The significant differences are: The State uses the more recent ANSI 92.2-1979 as the reference; adds requirements for specification and data display and placarding; adds requirements for elevation and reach determination and insulated aerial devices; and adds requirements for inspections. The State code was originally approved in the Federal Register (47 FR 5956) on February 9, 1982.

On its own initiative, the State of Washington has submitted by letter dated June 15, 1989, from Joseph A. Dear, Director, to James W. Lake, Regional Administrator, a State standard

for forklift elevated work platforms in construction. The State's submission, which is contained in WAC 296-155-48536, was adopted on May 15, 1989, effective June 30, 1989, under Administrative Order 89-03. National Office review revealed discrepancies and the submission was returned to the State for correction. On November 25, 1992, the State submitted a corrective amendment that made the changes requested by the National Office. This submission was adopted on October 30, 1992, effective December 8, 1992, under Washington Administrative Order 92-06.

On its own initiative, the State has submitted by letter dated February 9, 1990, from Joseph A. Dear, Director, to James W. Lake, Regional Administrator, a change to its previously approved Grain Elevator standards at WAC 296-99-015 and 050. The change to WAC 296-99-015 incorporated an OSHA determination contained in a March 27, 1989 memorandum from the Directorate of Compliance Programs that the standard does not apply to alfalfa processing plants that are not involved with grain handling. The change to WAC 296-99-050 incorporated a court decision to stay the 1/8 inch action level contained in 29 CFR 1910.272(i)(2). These changes were adopted on January 11, 1990, effective February 26, 1990, under Administrative Order 89-20. On June 20, 1991, a letter from Joseph A. Dear, Director, to James W. Lake, Regional Administrator, made another State-initiated change to WAC 296-99-050. This change made the State standard identical to the Federal standard 29 CFR 1910.272(i)(2). This change was necessary to incorporate the lifting of the stay by the courts to the 1/8 inch action level. This change was adopted on May 20, 1991, effective June 20, 1991, under Washington Administrative Order 91-01. The State standard was originally approved in the Federal Register (54 FR 7304) on February 17, 1989.

On its own initiative, the State submitted by letter dated October 29, 1993, from Mark O. Brown, Director, to James W. Lake, Regional Administrator, a State standard amendment comparable to 29 CFR 1910.1000, Table Z-3, Mineral Dusts. The significant difference is: the State lowered the permissible exposure limit for nuisance dust to 10 milligrams per cubic meter. The change was adopted under Administrative Order 92-15 on December 11, 1992 and became effective on January 15, 1993.

On its own initiative, the State of Washington has submitted by letters dated February 8, 1991, from Joseph A. Dear, Director, to James W. Lake,

Regional Administrator, amendments to its standards for Mechanical Power Presses, WAC 296-24-195; Powered Industrial Trucks, WAC 296-24-23023 and 296-24-23027; Cylinders and Containers, WAC 296-24-68203; Stairway Railings and Guards, WAC 296-24-75009; Railings, Toeboards, and Cover Specifications, WAC 296-24-75011; and Xenon Bulb Safety Procedures, WAC 296-24-95611. The amendments were made to incorporate previously approved Washington Regional Directives (WRDs). For Mechanical Power Presses, WRDs 78-38 and 79-25 were adopted in response to OSHA Directives STD 1-12.20 and 1-12.24 respectively. For Powered Industrial Trucks, WRDs 77-37 and 81-22 were adopted in response to OSHA Directives STD 1-11.3 and 1-11.7 respectively. For Railings, Toeboards, and Cover Specifications, WRD 81-18 was adopted in response to OSHA Directive STD 1-1.10. The WRDs for Cylinders and Containers, Stairway Railings and Guards and Xenon Bulbs were 79-43, 77-11 and 85-1, respectively, and were State-initiated. The State amendments were adopted on January 10, 1991, effective February 12, 1991, under Washington Administrative Order 90-18.

All of these State standards changes have been incorporated as part of the Washington State plan. All of the Washington Administrative Orders were adopted pursuant to RCW 34.04.040(2), 49.17.040, 49.17.050, Public Meetings Act RCW 42.30, Administrative Procedures Act RCW 34.04, and the State Register Act RCW 34.08.

2. *Decision.* OSHA has determined that the State standards and amendments for Hazardous Waste Operations and Emergency Response, Aerial Lifts, and Mineral Dusts are at least as effective as the comparable Federal standards, as required by Section 18(c)(2) of the Act. The Hazardous Waste amendments have been in effect since November 15, 1990, the Aerial Lifts standard has been in effect since September 10, 1992, and the Mineral Dusts amendment has been in effect since January 15, 1993. During this time OSHA has received no indication of significant objection to these different State standards either as to their effectiveness in comparison to the Federal standards or as to their conformance with product clause requirements of section 18(c)(2) of the Act. (A different State standard applicable to a product which is distributed or used in interstate commerce must be required by compelling local conditions and not unduly burden interstate commerce.)

OSHA has also determined that the differences between the State and Federal amendments for all the remaining standards in this notice are minimal and that these State standards amendments are thus substantially identical. OSHA therefore approves these standards; however, the right to reconsider this approval is reserved should substantial objections be submitted to the Assistant Secretary.

**3. Location of Supplement for Inspection and Copying.** A copy of the standards supplement, along with the approved plan, may be inspected and copied during normal business hours at the following locations: Office of the Regional Administrator, Occupational Safety and Health Administration, 1111 Third Avenue, Suite 715, Seattle, Washington 98101-3212; State of Washington Department of Labor and Industries, 7273 Linderson Way, S.W., Tumwater, Washington 98501; and the Office of State Programs, Occupational Safety and Health Administration, Room N-3700, 200 Constitution Avenue, NW, Washington, D.C. 20210.

**4. Public Participation.** Under 29 CFR 1953.2(c), the Assistant Secretary may prescribe alternative procedures to expedite the review process or for other good cause which may be consistent with applicable laws. The Assistant Secretary finds that good cause exists for not publishing the supplement to the Washington State Plan as a proposed change and making the Regional Administrator's approval effective upon publication for the following reason:

The standard amendments were adopted in accordance with the procedural requirements of State law and further public participation would be repetitious.

This decision is effective (Sec. 18, Pub. L. 91-596, 84 STAT. 6108 [29 U.S.C. 667]).

Signed at Seattle, Washington, this 28th day of April 1995.

Richard S. Terrill,

*Acting Regional Administrator.*

[FR Doc. 96-5010 Filed 3-4-96; 8:45 am]

BILLING CODE 4510-26-P

## **Pension and Welfare Benefits Administration**

[Application No. D-09986, et al.]

### **Proposed Exemptions NBD Bancorp**

**AGENCY:** Pension and Welfare Benefits Administration, Labor.

**ACTION:** Notice of proposed exemptions.

**SUMMARY:** This document contains notices of pendency before the

Department of Labor (the Department) of proposed exemptions from certain of the prohibited transaction restriction of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1986 (the Code).

### **Written Comments and Hearing Requests**

Unless otherwise stated in the Notice of Proposed Exemption, all interested persons are invited to submit written comments, and with respect to exemptions involving the fiduciary prohibitions of section 406(b) of the Act, requests for hearing within 45 days from the date of publication of this Federal Register Notice. Comments and request for a hearing should state: (1) the name, address, and telephone number of the person making the comment or request, and (2) the nature of the person's interest in the exemption and the manner in which the person would be adversely affected by the exemption. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing.

**ADDRESSES:** All written comments and request for a hearing (at least three copies) should be sent to the Pension and Welfare Benefits Administration, Office of Exemption Determinations, Room N-5649, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210. Attention: Application No. stated in each Notice of Proposed Exemption. The applications for exemption and the comments received will be available for public inspection in the Public Documents Room of Pension and Welfare Benefits Administration, U.S. Department of Labor, Room N-5507, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

### **Notice To Interested Persons**

Notice of the proposed exemptions will be provided to all interested persons in the manner agreed upon by the applicant and the Department within 15 days of the date of publication in the Federal Register. Such notice shall include a copy of the notice of proposed exemption as published in the Federal Register and shall inform interested persons of their right to comment and to request a hearing (where appropriate).

**SUPPLEMENTARY INFORMATION:** The proposed exemptions were requested in applications filed pursuant to section 408(a) of the Act and/or section

4975(c)(2) of the Code, and in accordance with procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, these notices of proposed exemption are issued solely by the Department.

The applications contain representations with regard to the proposed exemptions which are summarized below. Interested persons are referred to the applications on file with the Department for a complete statement of the facts and representations.

NBD Bancorp; Located in Detroit, Michigan; Proposed Exemption

[Application No. D-09986]

The Department is considering granting an exemption under the authority of section 408(a) of the Act and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted, the restrictions of section 406(b)(2) of the Act shall not apply to the merger of the INB Principal Stability Fund (the PS Fund) into the NBD Stable Asset Income Fund (the SAI Fund).<sup>1</sup>

The proposed exemption is conditioned upon satisfaction of the following requirements:

(1) On the date the merger is executed, the assets in the PS Fund and the assets in the SAI Fund will be valued in the same manner, under identical guidelines, by the same individuals;

(2) Upon completion of the merger of the PS Fund into the SAI Fund, the aggregate fair market value of the interests of the employee benefit plans (the Plans) participating in the SAI Fund immediately following the merger, together with any cash received in lieu of fractional units, equals the aggregate fair market value of each participating Plans' interest in such Funds immediately before the merger;

(3) The assets of each of the participating Plans are invested in the same type of investments both before and after the proposed merger;

(4) Neither NBD Bancorp nor any of its affiliates receives fees or commissions in connection with the merger;

<sup>1</sup> For purposes of this proposed exemption, the PS Fund and the SAI Fund described herein are collectively referred to as the Funds.

(5) The Plans will pay no sales commissions or fees, as a result of the transaction; and

(6) A fiduciary who is acting on behalf of each affected Plan and who is independent of and unrelated to NBD Bancorp and any of its affiliates receives advance written notice of the merger of the PS Fund into the SAI Fund.

#### Summary of Facts and Representations

1. The Plans involved in this proposed exemption are certain pension, profit sharing, or stock bonus plans which are exempt from Federal income taxation under section 501(a) of the Code by reason of qualifying under section 401(a) of the Code.

2. The proposed exemption is requested on behalf of National Bank of Detroit (herein referred to as NBD Michigan) and on behalf of NBD Bank, N.A. (herein referred to as NBD Indiana). NBD Michigan and NBD Indiana are national banking associations and members of an "affiliated group," as defined in section 1504 of the Code. NBD Michigan is a wholly-owned subsidiary of NBD Bancorp, a bank holding company with principal offices in Detroit, Michigan. NBD Indiana, with principal offices in Indianapolis, Indiana, is a wholly-owned subsidiary of NBD Indiana, Inc., another bank holding company. It is represented that since 1992, NBD Indiana, Inc. has also been wholly-owned by NBD Bancorp.

3. The SAI Fund and the PS Fund are common funds maintained for the collective investment of monies contributed thereto by the Plans. NBD Michigan and NBD Indiana, respectively, serve as trustees for the SAI Fund and the PS Fund. The SAI Fund is one of twenty-five (25) separate collective investment funds under a group trust now known as the National Bank of Detroit Investment Fund for Employee Benefit Plans (the NBD Pooled Fund) which was established on May 12, 1960, by the National Bank of Detroit, a predecessor of NBD Michigan, and which, as amended, is now maintained by NBD Michigan. The PS Fund is one of the collective investment funds under a group trust known as the INB National Bank Group Trust for Employee Pension and Profit-Sharing Trusts B (the INB Group Trust) which was established on July 18, 1990, by INB National Bank, a predecessor of NBD Indiana, and which, as amended, is now maintained by NBD Indiana.

4. Both the SAI Fund and the PS Fund have substantially identical investment objectives, and the assets of each are invested in similar types of guaranteed insurance contracts. As of September

26, 1994, approximately 405 Plans participated in the SAI Fund, and 83 Plans participated in the PS Fund. As of January 23, 1996, it is represented that there were 44 Plans participating in the PS Fund. The aggregate fair market value of the SAI Fund, as of September 30, 1994, was \$189,876,000. As of November 30, 1994, the aggregate fair market value of the PS Fund was approximately \$12,829,000.

5. In order to improve the administration of the SAI Fund and the PS Fund, thereby improving service to the Plans participating in those Funds, NBD Michigan and NBD Indiana desire to merge the SAI Fund and the PS Fund, with the SAI Fund being the surviving fund. It is represented that the trustees of the Plans which participate in the PS Fund were notified of the proposed merger of the PS Fund into the SAI Fund on or about July 1994. Such notification advised the Plans participating in the PS Fund of the right to withdraw from such fund and the rules and procedures applicable to such withdrawal. Plans under the terms of the guaranteed investment contracts held by the Funds are permitted to withdraw any or all of their investment upon twelve (12) months prior written notice. It is represented that from the time the notification was sent in July 1994, none of the Plans participating in the PS Fund expressed concern regarding the merger. It is represented that, if it had been inclined to do so, a Plan participating in the PS Fund could have submitted its withdrawal request at the time the notification was given in July 1994, (or even several months later), and could already have received a distribution of its interest in the PS Fund. In this regard, it is represented that none of the Plans participating in the PS Fund subsequently elected to withdraw as a result of the proposed merger.

Because NBD Michigan exercises authority and control over the assets of the SAI Fund, it is deemed to be a fiduciary with respect to each of the Plans participating in the SAI Fund. Similarly, because NBD Indiana exercises authority and control over the assets of the PS Fund, it is deemed to be a fiduciary with respect to each of the Plans participating in the PS Fund.

6. As fiduciaries, NBD Michigan and NBD Indiana believe that because of their affiliation in executing the merger of the PS Fund into the SAI Fund, they each may be acting on behalf of adverse parties to the Plans each represents; and thus, a violation of section 406(b)(2) of the Act may occur. Accordingly, NBD Michigan and NBD Indiana have requested an administrative exemption

from the prohibitions as set forth in section 406(b)(2) of the Act for the proposed transaction.

7. It is represented that the proposed merger is administratively feasible in that it constitutes a single transaction, the terms of which can be reviewed and approved in advance by the Department. Further, NBD Michigan and NBD Indiana will bear the cost of filing the application for exemption, the cost of notifying interested persons, and the expenses associated with the proposed transaction.

8. NBD Michigan and NBD Indiana have determined that the merger would be in the best interest of the Plans participating in the SAI Fund and the PS Fund. In this regard, the merger of the PS Fund and the SAI Fund will create a larger pool of assets which will result in better investment diversity and will increase the bargaining power of the SAI Fund when purchasing new contracts. It is anticipated that the increased size of the SAI Fund will create certain administrative efficiencies, and will serve to avoid or postpone any future fee increases. In addition, inasmuch as the SAI Fund has substantially greater liquidity than the PS Fund, Plans wishing to withdraw from the SAI Fund after the merger may be able to do so in as little as ninety (90) days, rather than twelve (12) months.

9. NBD Michigan and NBD Indiana have determined that the rights of the Plans participating in the Funds are protected in that the fair market value of the investment of each of the Plans in the Funds involved in the proposed transaction will not be changed as a result of the merger. In this regard, it is represented that the valuation methodology followed by both the PS Fund and the SAI Fund is identical, in that both of the Funds are valued daily and processed under the same guidelines by precisely the same individuals.

More specifically, it is represented that there are only two classes of assets in each of the Funds. The first class consists of cash held by each of the Funds in short-term money market funds. In this regard, the applicants maintain that although the interest rate earned in these money market fund varies, such money market funds are valued as cash. The second class of assets consists of various fixed rate and variable rate guaranteed investment contracts purchased by the Funds from highly rated insurance companies and held to term. It is represented that both the Funds hold fixed rate guaranteed investment contracts, and that only the SAI Fund holds variable rate guaranteed investment contracts. It is represented

that no default presently exists, nor has there previously been any default, under any guaranteed investment contract held by the Funds.

It is represented that these guaranteed investment contracts held by the Funds have been and will continue to be valued on the basis of the principal value plus accrued interest to the date of valuation calculated at the rate applicable to each contract through the date of valuation. In this regard, with respect to the four (4) variable rate guaranteed investment contracts held by the SAI Fund, it is represented that the rate of interest applicable to such contracts is determined and announced by the issuing insurance company on a monthly basis, and that the rate so determined is fixed for the following thirty (30) day period. For example, if the merger date were specified to be December 31, 1996, the applicable rate under each of these four (4) contracts as of that date would be fixed and certain, such that the contracts could be valued to that date using the established rate. Accordingly, the applicants represent that there is no significant benefit to be derived from an independent valuation of the assets held in the Funds, because the straightforward method by which the value of both the fixed rate and variable rate guaranteed investment contracts is determined can be readily verified by the Department and by the investors in the Funds.

10. It is represented that the merger will not create any additional fees for the Plans participating in the Funds. In this regard, neither NBD Michigan, NBD Indiana, nor any affiliated party will receive any fees or commissions with respect to the proposed merger, nor will the Plans pay any sales commissions or fees, as a result of the proposed transaction. Other than the incidental administrative efficiencies which will result from the merger of the PS Fund and the SAI Fund, it is represented that neither NBD Michigan and NBD Indiana nor any affiliated party will derive any financial benefit from the merger of the Funds.

It is represented that at the present time, NBD Michigan has employee benefit trust customers, including the Plans, which have assets invested in the SAI Fund, but NBD Michigan has no employee benefit trust customers invested in the PS Fund. It is further represented that at the present time, NBD Indiana has employee benefit trust customers, including the Plans, which have assets invested in the PS Fund, and some employee benefit trust customers which have already invested assets in the SAI Fund. The annual investment fee charged by NBD Indiana

to participants in either the SAI Fund or the PS Fund consists of an annual base fee of \$400, plus a market value based fee determined as follows: .85% on the first \$1 million; .50% on the next \$2 million; .35% on the next \$2 million; .25% on the next \$5 million; .15% on the next \$10 million; and .10% on the excess over \$20 million. The annual investment fee charged by NBD Michigan to participants in the SAI Fund is currently .75% of the market value of the SAI Fund.<sup>2</sup>

Following the merger of the PS Fund into the SAI Fund, both NBD Michigan and NBD Indiana will have employee benefit trust customers, including the Plans, participating in the SAI Fund. In this regard, it is represented that NBD Indiana and NBD Michigan will continue to service their respective employee benefit trust customers, including the Plans, and the investment fees charged to those Plans will be determined by the NBD Bancorp subsidiary (*i.e.* NBD Indiana or NBD Michigan) which originated that customer. Accordingly, it is represented that the investment fees, as described above, charged to the Plans by NBD Michigan and NBD Indiana, to the respective Plans that each services will not change following the merger of the PS Fund and the SAI Fund.

With respect to the amount of the investment fees charged to the Plans by NBD Michigan and NBD Indiana, the applicants point out that, although owned by a common parent corporation, NBD Michigan and NBD Indiana are separate corporations (one state-chartered and one federally-chartered) with separate fee schedules and separate customers served by employees of their separate trust departments. The applicants state that the fees charged by each bank include compensation for services relating to the administration of each of the Funds, such as acquiring the guaranteed investment contracts, performing valuations, and satisfying reporting and recordkeeping requirements, as well as compensation for the sales and consulting services provided by the separate staff of each bank to its respective trust clients. It is represented that the level of services, the personnel providing these services, and the overhead costs (*e.g.* rent,

<sup>2</sup> It is represented that NBD Michigan and NBD Indiana rely upon the statutory exemption, as set forth in section 408(b)(2) of the Act, for the receipt of fees for investment management services provided with respect to the Funds. The Department, herein, expresses no opinion as to whether the provision of services by NBD Michigan and NBD Indiana to the Funds and the compensation received therefore satisfy the terms and conditions, as set forth in section 408(b)(2) of the Act.

compensation levels, etc.) associated with the provision of such services is entirely different for each bank. Further, it is represented that the separate fee schedules of NBD Michigan and NBD Indiana, as described above, are primarily a function of the different markets served by each bank, and are intended to be responsive to and competitive with the fees charged by other financial institutions in the area in which each bank operates. In this regard, both NBD Michigan and NBD Indiana maintain that their respective fee structures are reasonable and competitive with the other institutions in the markets they each serve.<sup>3</sup>

11. To accomplish the merger of the SAI Fund and the PS Fund, the assets of the Funds (including all accrued income) will be valued as of the date the merger is executed (the Merger Date). The Merger Date will be declared by NBD Michigan and NBD Indiana following the grant of this proposed exemption. As of the Merger Date, NBD Indiana will transfer all of the assets of the PS Fund to NBD Michigan, as trustee of the SAI Fund. It is represented that all of the assets of the PS Fund meet the investment criteria of the SAI Fund, and accordingly, the SAI Fund will accept the transfer of all of the assets of the PS Fund, without exception. As all of the assets of the PS Fund will be transferred to the SAI Fund, the PS Fund will cease to exist immediately following the merger.

The transferred assets will be commingled for investment following the Merger Date, and all income will be deemed to have been earned in the SAI Fund. The Plans which participated in the PS Fund immediately preceding the merger will become participants in the SAI Fund, as of the Merger Date. Each of the Plans participating in the PS Fund immediately preceding the merger will have allocated to it, as of the Merger Date, the proportion of the allocated units in the SAI Fund equal to its proportion of units in the PS Fund immediately preceding the merger. No fractional units of participation in the SAI Fund will be issued in the merger. The SAI Fund will pay cash equal to the fair market value of any such fractional unit to which each of the participating Plans in the PS Fund would otherwise be entitled.

<sup>3</sup> ERISA's general standards of fiduciary conduct would apply to the investment of plan assets in the SAI Fund. Accordingly, the plan fiduciary must act prudently with respect to its decision to enter into a new compensation arrangement, which under the particular facts and circumstances, may result in the plan paying additional amounts for similar investment services.

12. In summary, it is represented that the proposed transactions will satisfy the statutory criteria for an exemption under section 408(a) of the Act because:

(a) on the date the merger is executed, the assets in the PS Fund and the assets in the SAI Fund will be valued in the same manner, under identical guidelines, by the same individuals;

(b) the fair market value of the interests of the Plans participating in the affected Funds will remain unchanged as a result of the proposed merger;

(c) the assets of each participating Plan will be invested in the same type of investment both before and after the execution of the merger;

(d) the proposed merger will result in greater operational efficiencies and economies of scale, as well as greater opportunities for investment diversification;

(e) neither NBD Bancorp nor any of its affiliates will receive any fees or commissions in connection with the proposed merger;

(f) the Plans will pay no sales commissions or fees, as a result of the transaction; and

(g) A fiduciary who is acting on behalf of each affected Plan and who is independent of and unrelated to NBD Bancorp and any of its affiliates has received advance written notice of the merger of the PS Fund into the SAI Fund.

#### Notice to Interested Persons

The applicant maintains that persons who may be interested in the pendency of the requested exemption include the independent fiduciaries of all of the Plans participating under the NBD Pooled Fund and the INB Group Trust. It is represented within fifteen (15) days of the date of publication of the Notice of Proposed Exemption (the Notice) in the Federal Register, that notification in writing of the Notice will be provided by mail to the independent fiduciaries of all of the Plans participating under the NBD Pooled Fund and the INB Group Trust. Such notification will include a copy of the Notice, as published in the Federal Register, and a copy of the supplemental statement, as required, pursuant to 29 CFR 2570.43(b)(2). The notification will inform such interested persons of their right to comment or request a hearing within a time period specified in the notification.

**FOR FURTHER INFORMATION CONTACT:** Ms. Angelena C. Le Blanc of the Department (202) 219-8883. (This is not a toll-free number.)

Biscayne Bay Pilots, Inc. Money Purchase Pension Plan (M/P Plan) and Biscayne Bay Pilots, Inc. 401(k) Profit Sharing Plan (P/S Plan; Collectively, the Plans); Located in Miami, Florida; Proposed Exemption

[Application Nos. D-10036 and D-10037]

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 C.F.R. Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990.) If the exemption is granted, the restrictions of sections 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the proposed sale of certain improved real property (the Property) by a trust (the HK Trust) established on behalf of Helge Krarup (Mr. Krarup) within the Plans to Mr. Krarup, a party in interest with respect to the Plans; provided that the following conditions are satisfied:

(a) the proposed sale will be a one-time cash transaction;

(b) the HK Trust will receive the current fair market value for the Property established at the time of the sale by an independent qualified appraiser;

(c) the HK Trust will pay no expenses associated with the sale;

(d) the sale will provide the HK Trust with liquidity; and

(e) only the assets in the HK Trust will be affected by the transaction.

#### Summary of Facts and Representations

1. The Plans were established January 1, 1989. The M/P Plan and the P/S Plan are defined contribution plans. As of March 31, 1995, the M/P Plan had 25 participants and the P/S Plan had 26 participants. As of March 31, 1995, the Plans had aggregate net assets of \$944,804.67. Biscayne Bay Pilots, Inc. (Biscayne Bay) is the sponsor of the Plans.

Biscayne Bay is a Florida corporation in the business of providing support services to Biscayne Bay Pilots Association (the Association), which furnishes harbor pilot support services to ships in the Port of Miami. Once a pilot is licensed by the State of Florida, a pilot sets up a corporation of which he is the sole officer, director, shareholder and employee. Currently, there are fifteen separate pilot corporations (the Pilot Corporations), which make up the partners of the Association. Biscayne Bay and the Pilot Corporations constitute an affiliated

service group under section 414(m) of the Internal Revenue Code of 1986.

Biscayne Bay and the Pilot Corporations have all adopted the Plans. The Plans' trustees are Stephen E. Nadeau, William M. Breese and John R. Fernandez, who respectively are the President, the Vice-President, and the Secretary of Biscayne Bay. Each participant in the Plans can elect to, among other things, establish their own trust within the Plans using only their funds to fund the trust. This trust contains the participant's funds within the two Plans, and the participants are required to bear the expenses associated with investing in their own trust. HK Trust is such a trust containing only the assets in Mr. Krarup's accounts in the Plans.

2. Helge Krarup, Inc. (HK Inc.) is a Florida corporation that was formed on August 26, 1981. Mr. Krarup is the sole officer, director and shareholder of HK Inc. On June 9, 1989, HK Inc. established the HK Trust as a trust within the Plans. HK Trust has one participant, Mr. Krarup. Mr. Krarup's account balances in the Plans were deposited in the HK Trust. The trustees of the HK Trust are Mr. Krarup and his wife Bente Krarup. As of December 31, 1994, the HK Trust had net assets of \$565,444.

3. In December 1983, the Helge Krarup, Inc. Defined Benefit Pension Plan (the HK Plan) <sup>4</sup> purchased the Property from Kenneth and Eunice Stein (the Steins), who were unrelated third parties, for \$245,000 plus appropriate closing costs. The Property contains a residence (the Residence) which is located on two acres of land. The HK Plan made a down payment in the amount of \$40,000 and took a mortgage secured by the Property for the remaining \$205,000 from the Steins. The mortgage had a duration of fifteen years (15) and an interest rate of 12% per annum. The applicant represents that accelerated payments were made under the mortgage and the mortgage was paid off by August 15, 1987. Mr. Krarup as the trustee and the sole participant of the HK Plan, made the decision to purchase the Property as a long-term investment for the HK Plan. It is represented that the Property is not adjacent to any real property owned by Mr. Krarup or any other party in interest, and that the Property has never been used by a party in interest. As of December 31, 1983, the Property

<sup>4</sup> Mr. Krarup was the only participant in the HK Plan.



represented in excess of 90% of the HK Plan's total assets.<sup>5</sup>

4. When the HK Plan was terminated, the two deeds evidencing the Property were transferred to the HK Trust on February 28, 1990. The applicant represents that there were two deeds because the Property was described on the original deed in two parcels. Accordingly, one deed was done for each parcel. The applicant states that at the time of the transfer, the Property constituted approximately 65% of the HK Trust's total assets. Currently, the Property is not encumbered by debt and is owned outright by the HK Trust.

5. The Property, located at 1510 NE Dixie Highway, Jensen Beach, Florida, was appraised on June 19, 1995 (the Appraisal). The Appraisal was prepared by Mary Ann Haskell and by Daniel K. Deighan, MAI, independent Florida state certified appraisers (the Appraisers), who are with Deighan Appraisal Associates, Inc. The Appraisers indicated that the Residence on the Property has not been adequately maintained, and as of the date of inspection there was evidence of roof leaks in both of the upstairs bedrooms and of extensive wood rot on the enclosed porch. Because of deferred maintenance and other deficiencies, the structure of the Residence is considered to be in "tear down" condition and contributes little to the overall value of the Property. The Appraisers relied primarily on the Sales Comparison approach, as supported by the Cost Approach, and determined that as of June 19, 1995, the "as is" market value of the Property was \$210,000. The Appraisers stated that the Income approach was considered inapplicable due to insufficient rental data in this market.

6. Furthermore, the applicant also contacted Johnson & Johnson, a local real estate firm (the J&J Firm), regarding prospects of increasing rentals on the Property or selling the Property. In this regard, Ms. Kim Johnson of the J&J Firm, made the following observations: among other things, the Residence is very old and rundown, and any prospective purchaser would buy the Property solely for the land value and would not consider the Residence to be of any value. Furthermore, the shape of the

Property is very irregular and it might be difficult to fit a large house on the Property, even though the Property is over two acres in size. In the last year in the immediate area of the Property, there has been only one purchase of a large ocean front lot, which was on the market for a significant period of time before it sold. Ms. Johnson believes that the Property could take a year or more to sell for approximately \$300,000, and the real estate commission would be approximately 6% and the closing costs would be approximately 1% to be paid by the seller.

6. The applicant represents that the Property has been leased since April 1984 to unrelated third parties. The Property is currently leased under a month-to-month agreement to Kim Johnson and Chris Tyler, who are unrelated third parties, for a rental amount of \$650 per month. The applicant maintains that the fair rental value of the Property was determined by establishing the rentals charged for houses of similar size and with similar amenities in the area. Because the Property has been rented, the applicant submitted a "return on investment" analysis for the Property, covering the period 1984 through 1994. Return on investment value ratios were derived by the applicant by dividing net income by the original acquisition price of the Property for each year of ownership. An average of the "return on investment" figures was determined to be approximately one percent (1%). Also, in this regard, the total expenses during the period 1984-94 sustained by the HK Trust for the Property were approximately \$51,303, and the total income received by the HK Trust during this period was approximately \$67,116. Therefore, the net income received by the HK Trust for the Property during 1984-94 was \$15,813 (\$67,116-\$51,303).

7. Mr. Krarup now proposes to purchase the Property from the HK Trust in a one-time cash transaction. The applicant represents that the proposed transaction is in the best interest and protective of the HK Trust because the HK Trust will pay no expenses or commissions associated with the sale. Also, the fair market value of the Property has been determined by the independent qualified Appraisers to be \$210,000. In this regard, Mr. Krarup will pay the HK Trust the current fair market value for the Property established at the time of the sale by the independent qualified Appraisers. The sale of the Property will increase the liquidity of the HK Trust's portfolio. The sale will also enable the HK Trust to sell an illiquid asset which currently

represents approximately 45% of the HK Trust's total assets and which has depreciated in value over time. It is represented that because the HK Trust is a one participant trust within the Plans, no other participant in the Plans will be affected by the proposed transaction.

8. In summary, the applicant represents that the transaction satisfies the statutory criteria of section 408(a) of the Act and section 4975(c)(2) of the Code because:

(a) the proposed sale will be a one-time cash transaction;

(b) the HK Trust will receive the current fair market value for the Property established at the time of the sale by the independent qualified Appraisers;

(c) the HK Trust will pay no expenses associated with the sale;

(d) the sale will provide the HK Trust with liquidity; and

(e) only the assets in the HK Trust will be affected by the transaction.

#### Notice To Interested Persons

Because Mr. Krarup is the sole participant of the HK Trust, it has been determined that there is no need to distribute the notice of proposed exemption to interested persons. Comments and requests for a hearing are due 30 days from the date of publication of this notice in the Federal Register.

**FOR FURTHER INFORMATION CONTACT:** Ekaterina A. Uzylyan of the Department at (202) 219-8883. (This is not a toll-free number.)

Society National Bank; KeyTrust Company of Ohio; Society Asset Management, Inc; and KeyCorp; Located in Cleveland, Ohio; Proposed Exemption

[Application No. D-10063]

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990).

#### Section I—Exemption for In-Kind Transfer of CIF Assets

If the exemption is granted, the restrictions of section 406(a) and 406(b) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (F) of the Code, shall not apply as of December 1, 1993, to the in-kind transfer of assets of plans for which Society National Bank, KeyTrust Company of Ohio, N.A., Society Asset Management, Inc., and KeyCorp or an affiliate (collectively, the Bank) serves as a fiduciary (the Client Plans), other

<sup>5</sup> The Department notes that the decisions to transfer and hold the Property by the HK Trust, as well as the maintaining and renting of the Property by the HK Trust are governed by the fiduciary responsibility requirements of Part 4, Subtitle B, Title I of the Act, and the Department herein is not providing relief for any violations of Part 4 which may have arisen as a result of these fiduciary decisions. Accordingly, this exemption extends relief only for the proposed sale of the Property to Mr. Krarup.



than plans established and maintained by the Bank, that are held in certain collective investment funds maintained by the Bank (the CIFs), in exchange for shares of The Victory Portfolios (collectively, the Funds), an open-end investment company registered under the Investment Company Act of 1940 (the 1940 Act), for which the Bank acts as an investment adviser as well as a custodian, sub-administrator, and/or shareholder servicing agent, or provides some other "secondary service" as defined in Section IV(h), in connection with the termination of such CIFs, provided that the following conditions and the general conditions of Section III below are met:

(a) No sales commissions or other fees are paid by the Client Plans in connection with the purchase of Fund shares through the in-kind transfer of CIF assets and no redemption fees are paid in connection with the sale of such shares by the Client Plans to the Funds.

(b) All or a pro rata portion of the assets of a CIF are transferred to a Fund in exchange for shares of such Fund.

(c) Each Client Plan receives shares of a Fund which have a total net asset value that is equal to the value of the Client Plan's pro rata share of the assets of the CIF on the date of the transfer, based on the current market value of the CIF's assets, as determined in a single valuation performed in the same manner at the close of the same business day, using independent sources in accordance with Rule 17a-7(b) of the Securities and Exchange Commission (SEC) under the 1940 Act and the procedures established by the Funds pursuant to Rule 17a-7 for the valuation of such assets. Such procedures must require that all securities for which a current market price cannot be obtained by reference to the last sale price for transactions reported on a recognized securities exchange or NASDAQ be valued based on an average of the highest current independent bid and lowest current independent offer, as of the close of business on the Friday preceding the weekend of the CIF transfers, determined on the basis of reasonable inquiry from at least three sources that are broker-dealers or pricing services independent of the Bank.

(d) A second fiduciary who is independent of and unrelated to the Bank (the Second Fiduciary) receives advance written notice of the in-kind transfer of assets of the CIFs and full written disclosure of information concerning the Funds, including:

(1) A current prospectus for each Fund in which a Client Plan is considering investing;

(2) A statement describing the fees for investment advisory or similar services, any secondary services as defined in Section IV(h), and all other fees to be charged to or paid by the Client Plan and by the Funds, including the nature and extent of any differential between the rates of such fees;

(3) The reasons why the Bank considers investing in the Fund is an appropriate investment decision for the Client Plan;

(4) A statement describing whether there are any limitations applicable to the Bank with respect to which assets of a Client Plan may be invested in a Fund, and, if so, the nature of such limitations; and

(5) Upon request of the Second Fiduciary, a copy of the proposed exemption and/or a copy of the final exemption, if granted, once such documents are published in the Federal Register.

(e) After consideration of the foregoing information, the Second Fiduciary authorizes in writing the in-kind transfer of the Client Plan's CIF assets to a corresponding Fund in exchange for shares of the Fund.

(f) For all in-kind transfers of CIF assets to a Fund following the publication of this proposed exemption in the Federal Register, the Bank sends by regular mail to each affected Client Plan the following information:

(1) Within 30 days after completion of the transaction, a written confirmation containing:

(i) The identity of each security that was valued for purposes of the transaction in accordance with Rule 17a-7(b)(4);

(ii) The price of each such security involved in the transaction;

(iii) The identity of each pricing service or market-maker consulted in determining the value of such securities; and

(2) Within 90 days after completion of each in-kind transfer, a written confirmation containing:

(i) The number of CIF units held by the Client Plan immediately before the transfer, the related per unit value, and the total dollar amount of such CIF units; and

(ii) The number of shares in the Funds that are held by the Client Plan following the transfer, the related per share net asset value, and the total dollar amount of such shares.

(g) The conditions set forth in paragraphs (e), (f) and (n) of Section II below are satisfied.

## Section II—Exemption for Receipt of Fees

If the exemption is granted, the restrictions of sections 406(a) and 406(b) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (F) of the Code, shall not apply as of October 1, 1995 to: (1) the receipt of fees by the Bank from the Funds for acting as an investment adviser to the Funds in connection with the investment by the Client Plans in shares of the Funds; and (2) the receipt and retention of fees by the Bank from the Funds for acting as custodian, sub-administrator and shareholder servicing agent to the Funds, as well as for providing any other services to the Funds which are not investment advisory services (i.e. "secondary services"), in connection with the investment by the Client Plans in shares of the Funds, provided that the following conditions and the general conditions of Section III are met:

(a) No sales commissions are paid by the Client Plans in connection with the purchase or sale of shares of the Funds and no redemption fees are paid in connection with the sale of shares by the Client Plans to the Funds.

(b) The price paid or received by a Client Plan for shares in a Fund is the net asset value per share at the time of the transaction, as defined in Section IV(e), and is the same price which would have been paid or received for the shares by any other investor at that time.

(c) The Bank, including any officer or director of the Bank, does not purchase or sell shares of the Funds to any Client Plan.

(d) Each Client Plan receives a credit, either through cash or the purchase of additional shares of the Funds pursuant to an annual election made by the Client Plan, of such Plan's proportionate share of all fees charged to the Funds by the Bank for investment advisory services, including any investment advisory fees paid by the Bank to third party sub-advisors, within no more than one business day of the receipt of such fees by the Bank.

(e) For each Client Plan, the combined total of all fees received by the Bank for the provision of services to the Client Plan, and in connection with the provision of services to the Funds in which the Client Plan may invest, is not in excess of "reasonable compensation" within the meaning of section 408(b)(2) of the Act.<sup>6</sup>

<sup>6</sup>In addition, the Department notes that Section 404(a) of the Act requires, among other things, that

(f) The Bank does not receive any fees payable pursuant to Rule 12b-1 under the 1940 Act in connection with the transactions.

(g) The Client Plans are not employee benefit plans sponsored or maintained by the Bank.

(h) The Second Fiduciary receives, in advance of any initial investment by the Client Plan in a Fund, full and detailed written disclosure of information concerning the Funds, including but not limited to:

(1) A current prospectus for each Fund in which a Client Plan is considering investing;

(2) A statement describing the fees for investment advisory or similar services, any secondary services as defined in Section IV(h), and all other fees to be charged to or paid by the Client Plan and by the Funds, including the nature and extent of any differential between the rates of such fees;

(3) The reasons why the Bank may consider such investment to be appropriate for the Client Plan;

(4) A statement describing whether there are any limitations applicable to the Bank with respect to which assets of a Client Plan may be invested in the Funds, and if so, the nature of such limitations; and

(5) Upon request of the Second Fiduciary, a copy of the proposed exemption and/or a copy of the final exemption, if granted, once such documents are published in the Federal Register.

(i) After consideration of the information described above in paragraph (h), the Second Fiduciary authorizes in writing the investment of assets of the Client Plan in each particular Fund, the fees to be paid by such Funds to the Bank, and the purchase of additional shares of a Fund by the Client Plan with the fees credited to the Client Plan by the Bank.

(j) All authorizations made by a Second Fiduciary regarding investments in a Fund and the fees paid to the Bank are subject to an annual reauthorization wherein any such prior authorization

referred to in paragraph (i) shall be terminable at will by the Client Plan, without penalty to the Client Plan, upon receipt by the Bank of written notice of termination. A form expressly providing an election to terminate the authorization described in paragraph (i) above (the Termination Form) with instructions on the use of the form must be supplied to the Second Fiduciary no less than annually; provided that the Termination Form need not be supplied to the Second Fiduciary pursuant to this paragraph sooner than six months after such Termination Form is supplied pursuant to paragraph (l) below, except to the extent required by such paragraph in order to disclose an additional service or fee increase. The instructions for the Termination Form must include the following information:

(1) The authorization is terminable at will by the Client Plan, without penalty to the Client Plan, upon receipt by the Bank of written notice from the Second Fiduciary; and

(2) Failure to return the Termination Form will result in continued authorization of the Bank to engage in the transactions described in paragraph (i) on behalf of the Client Plan.

(k) The Second Fiduciary of each Client Plan invested in a particular Fund receives full written disclosure, in a statement separate from the Fund prospectus, of any proposed increases in the rates of fees charged by the Bank to the Funds for secondary services (as defined in Section IV(h) below) at least 30 days prior to the effective date of such increase, accompanied by a copy of the Termination Form, and receives full written disclosure in a Fund prospectus or otherwise of any increases in the rates of fees charged by the Bank to the Funds for investment advisory services even though such fees will be credited as required by paragraph (d) above.

(l) In the event that the Bank provides an additional secondary service to a Fund for which a fee is charged or there is an increase in the amount of fees paid by the Funds to the Bank for any secondary services resulting from a decrease in the number or kind of services performed by the Bank for such fees in connection with a previously authorized secondary service, the Bank will, at least thirty days in advance of the implementation of such additional service or fee increase, provide written notice to the Second Fiduciary explaining the nature and the amount of the additional service for which a fee will be charged or the nature and amount of the increase in fees of the affected Fund. Such notice shall be

accompanied by the Termination Form, as defined in Section IV(i) below.

(m) On an annual basis, the Bank provides the Second Fiduciary of a Client Plan investing in the Funds with:

(1) A copy of the current prospectus for the Funds and, upon such fiduciary's request, a copy of the Statement of Additional Information for such Funds which contains a description of all fees paid by the Funds to the Bank;

(2) A copy of the annual financial disclosure report of the Funds in which such Client Plan is invested which includes information about the Fund portfolios as well as audit findings of an independent auditor within 60 days of the preparation of the report; and

(3) Oral or written responses to inquiries of the Second Fiduciary as they arise.

(n) All dealings between the Client Plans and the Funds are on a basis no less favorable to the Client Plans than dealings with other shareholders of the Funds.

### Section III—General Conditions

(a) The Bank maintains for a period of six years the records necessary to enable the persons described below in paragraph (b) to determine whether the conditions of this exemption have been met, except that (1) a prohibited transaction will not be considered to have occurred if, due to circumstances beyond the control of the Bank, the records are lost or destroyed prior to the end of the six-year period, and (2) no party in interest other than the Bank shall be subject to the civil penalty that may be assessed under section 502(i) of the Act or to the taxes imposed by section 4975 (a) and (b) of the Code if the records are not maintained or are not available for examination as required by paragraph (b) below.

(b)(1) Except as provided in paragraph (b)(2) and notwithstanding any provisions of section 504 (a)(2) and (b) of the Act, the records referred to in paragraph (a) are unconditionally available at their customary location for examination during normal business hours by—

(i) Any duly authorized employee or representative of the Department or the Internal Revenue Service,

(ii) Any fiduciary of the Client Plans who has authority to acquire or dispose of shares of the Funds owned by the Client Plans, or any duly authorized employee or representative of such fiduciary, and

(iii) Any participant or beneficiary of the Client Plans or duly authorized employee or representative of such participant or beneficiary;

a fiduciary of a plan act prudently, solely in the interest of the plan's participants and beneficiaries, and for the exclusive purpose of providing benefits to participants and beneficiaries when making investment decisions on behalf of a plan. Thus, the Department believes that the Bank should ensure, prior to any investments made by a Client Plan for which it acts as a trustee or investment manager, that all fees paid by the Funds, including fees paid to parties unrelated to the Bank and its affiliates, are reasonable. In this regard, the Department is providing no opinion as to whether the total fees to be paid by a Client Plan to the Bank, its affiliates, and third parties under the arrangements described herein would be either reasonable or in the best interests of the participants and beneficiaries of the Client Plans.

(2) None of the persons described in paragraph (b)(1) (ii) and (iii) shall be authorized to examine trade secrets of the Bank, or commercial or financial information which is privileged or confidential.

#### Section IV—Definitions

For purposes of this proposed exemption:

(a) The term "Bank" includes Society National Bank, KeyTrust Company of Ohio, Society Asset Management, Inc., KeyCorp and any affiliate thereof as defined below in paragraph (b)(1) of this section.

(b) An "affiliate" of a person includes:

(1) Any person directly or indirectly through one or more intermediaries, controlling, controlled by, or under common control with the person;

(2) Any officer, director, employee, relative, or partner in any such person; and

(3) Any corporation or partnership of which such person is an officer, director, partner, or employee.

(c) The term "control" means the power to exercise a controlling influence over the management or policies of a person other than an individual.

(d) The term "Fund" or "Funds" shall include the Victory Portfolios, or any other diversified open-end investment company or companies registered under the 1940 Act for which the Bank serves as an investment adviser and may also serve as a custodian, shareholder servicing agent, transfer agent or provide some other "secondary service" (as defined below in paragraph (h) of this Section) which has been approved by such Funds.

(e) The term "net asset value" means the amount for purposes of pricing all purchases and sales calculated by dividing the value of all securities, determined by a method as set forth in the Fund's prospectus and statement of additional information, and other assets belonging to the Fund or portfolio of the Fund, less the liabilities charged to each such portfolio or Fund, by the number of outstanding shares.

(f) The term "relative" means a "relative" as that term is defined in section 3(15) of the Act (or a "member of the family" as that term is defined in section 4975(e)(6) of the Code), or a brother, a sister, or a spouse of a brother or a sister.

(g) The term "Second Fiduciary" means a fiduciary of a Client Plan who is independent of and unrelated to the Bank. For purposes of this exemption, the Second Fiduciary will not be deemed to be independent of and unrelated to the Bank if:

(1) Such fiduciary directly or indirectly controls, is controlled by, or is under common control with the Bank;

(2) Such fiduciary, or any officer, director, partner, employee, or relative of the fiduciary is an officer, director, partner or employee of the Bank (or is a relative of such persons) or any affiliate thereof;

(3) Such fiduciary directly or indirectly receives any compensation or other consideration for his or her own personal account in connection with any transaction described in this exemption.

If an officer, director, partner, employee of the Bank (or relative of such persons), or affiliate thereof, is a director of such Second Fiduciary, and if he or she abstains from participation in (i) the choice of the Client Plan's investment adviser, (ii) the approval of any such purchase or sale between the Client Plan and the Funds, and (iii) the approval of any change in fees charged to or paid by the Client Plan in connection with any of the transactions described in Sections I and II above, then paragraph (g)(2) of this section shall not apply.

(h) The term "secondary service" means a service other than an investment management, investment advisory, or similar service, which is provided by the Bank to the Funds. For purposes of this proposed exemption, the term "secondary service" will include securities lending services provided by the Bank to the Funds, but will not include any brokerage services provided to the Funds by the Bank for the execution of securities transactions engaged in by the Funds.

(i) The term "Termination Form" means the form supplied to the Second Fiduciary which expressly provides an election to the Second Fiduciary to terminate on behalf of a Client Plan the authorization described in paragraph (j) of Section II. Such Termination Form may be used at will by the Second Fiduciary to terminate an authorization without penalty to the Client Plan and to notify the Bank in writing to effect a termination by selling the shares of the Funds held by the Client Plan requesting such termination within one business day following receipt by the Bank of the form; provided that if, due to circumstances beyond the control of the Bank, the sale cannot be executed within one business day, the Bank shall have one additional business day to complete such sale.

**EFFECTIVE DATE:** This proposed exemption, if granted, will be effective as of December 1, 1993, for the transactions described in Section I

above, and October 1, 1995, for the transactions described in Section II above.

#### Summary of Facts and Representations

1. The applicants described herein are Society National Bank (SNB), a national banking association, KeyTrust Company of Ohio, N.A. (KeyTrust), Society Asset Management, Inc. (SAM), and KeyCorp and its subsidiaries, including affiliates of SNB, KeyTrust, and SAM. Specifically, the exemption request is being made on behalf of: (i) SNB as former trustee of certain collective investment funds under the 1993 Amendment and Restatement of the Plan of the Retirement Trust of the Ameritrust Company National Association (the SNB-Ameritrust Collective Trust) and the 1993 Amendment and Restatement of Declaration of Trust Establishing Society National Bank Multiple Investment Trust for Employee Benefit Trusts (the SNB Collective Trust); (ii) KeyTrust, a wholly-owned subsidiary of SNB and, effective January 1, 1995, successor to SNB's trust operations and successor trustee of SNB-Ameritrust Collective Trust and SNB Collective Trust (SNB, prior to January 1, 1995 and KeyTrust, after January 1, 1995, are hereafter referred to as either "the Bank" or "the Trustee"); (iii) SAM, an Ohio Corporation, a wholly-owned subsidiary of KeyCorp Asset Management Holdings, Inc., which is a wholly-owned subsidiary of the Bank; and (iv) KeyCorp, an Ohio Corporation of which the Bank is a wholly-owned subsidiary. KeyCorp is a bank holding company that owns directly or indirectly a number of subsidiaries, which together constitute a controlled group of corporations within the meaning of section 414(b) of the Code. Thus, KeyCorp and its various subsidiaries are included herein within the definition of the term "Bank" (see Section IV(a) above).

2. The Bank is a trustee and, primarily through SAM, is an investment manager for a number of employee benefit plans subject to Title I of the Act as well as Keogh plans and individual retirement accounts (i.e. the Client Plans). The Bank is also trustee of two employee benefit plans sponsored by the Bank (the Bank Plans). The Bank has caused these plans to invest in certain collective investment funds (i.e. the CIFs) which are maintained by the Bank as trustee of the SNB-Ameritrust Collective Trust and the SNB Collective Trust. In December, 1993, the Bank liquidated certain of the CIFs and, to the extent practicable, distributed the assets held in such CIFs to the Plans.

In the case of assets distributed by the CIFs to each Client Plan with respect to which an independent fiduciary had consented to the transaction, the Bank immediately used the distributed assets to purchase shares of the Funds. Before the distribution of assets from the CIFs and the closing of the purchase transactions (the Fund Transactions), the applicant states that the Bank complied with the requirements of Prohibited Transaction Exemption (PTE) 77-3, 42 FR 18734 (April 8, 1977), with respect to the Bank Plans, and PTE 77-4, 42 FR 18732 (April 8, 1977), with respect to the Client Plans.<sup>7</sup>

Before the Fund Transactions, the CIFs consisted of six separate collective investment funds maintained by the Bank under the SNB Collective Trust, and eleven separate collective investment funds maintained by the Bank under the SNB-Ameritrust Collective Trust. The assets used to purchase shares of the Funds in the Fund Transactions consisted of assets distributed by four of the CIFs under the SNB Collective Trust and eight of the CIFs under the SNB-Ameritrust Collective Trust.

The Bank contemplates that in the future similar transactions structured either identically to the Fund

Transactions or in the form of an in-kind transfer of assets from CIFs to the Funds, with no intermediate distribution to the Client Plans, may be in the best interests of the Client Plans. In this regard, the Bank proposes to modify the manner in which it receives approval from independent fiduciaries of the Client Plans for changes in its fees and any fees received by other affiliates of the Bank from the Funds (as discussed below).

3. The Funds are a Massachusetts business trust operating as an open-end investment management company registered under the 1940 Act. The Bank, through SAM, serves as the investment adviser to each of the Funds that received assets from Plans in the Fund Transactions. The Bank receives investment advisory fees from the Funds for its investment advisory services under the terms of an investment advisory agreement adopted in accordance Section 15 of the 1940 Act. The Bank performs services for the Funds as shareholder servicing agent, sub-administrator and custodian. Both the Funds and the service agreements between the Fund and the Bank, including any fee arrangements, are described in prospectuses for the Funds.

4. The Winsbury Company is the distributor, administrator and principal underwriter of the Funds. The Winsbury Service Corporation, an affiliate of The Winsbury Company, serves as transfer agent and provides accounting services to the Funds. Neither The Winsbury Company nor The Winsbury Service Corporation are affiliates of the Bank.

#### *The Fund Transactions*

5. In December 1993, the Bank, acting as trustee or investment manager of the Plans, withdrew the assets held in the CIFs for the benefit of the Plans. For each Client Plan for which the consent of an independent fiduciary was given, the assets were then used to purchase shares of a Fund with investment objectives similar to the CIF that had distributed the assets. Each Client Plan received shares of each Fund in consideration for, and in proportion to, its share of the assets used to purchase shares of the Fund and with a value equal to the value of those assets at the time of the Fund Transactions. The CIFs from which assets were distributed, and the corresponding Fund, which has similar investment objectives, are as follows:

CIF	Fund
EB Balanced .....	Fund Balanced Fund.
EB Capital Appreciation Fund .....	Special Growth Stock Fund.
EB Equity Index Fund .....	Stock Index Fund.
EB Fixed Income Fund .....	Investment Quality Bond Fund.
EB Government Mortgage Fund .....	U.S. Government Income Fund.
EB Growth Equity Fund .....	Growth Stock Fund.
EB Intermediate Bond Fund .....	Intermediate Income Fund.
EB Intermediate Fixed Bond Fund .....	Intermediate Income Fund.
EB Small Capitalization Growth .....	Special Growth Stock Fund.
EB Small Capitalization Value Fund .....	Special Value Stock Fund.
EB Technology Fund .....	Special Value Stock Fund.
EB Value Fund .....	Value Stock Fund.

All of the Funds, other than the U.S. Government Income Fund, were established in connection with the Fund Transactions and held no assets before the Fund Transactions.

<sup>7</sup> PTE 77-3 permits the acquisition or sale of shares of a registered, open-end investment company by an employee benefit plan covering only employees of such investment company, employees of the investment adviser or principal underwriter for such investment company, or employees of any affiliated person (as defined therein) of such investment adviser or principal underwriter, provided certain conditions are met.

PTE 77-4, in pertinent part, permits the purchase and sale by an employee benefit plan of shares of a registered, open-end investment company when a fiduciary with respect to the plan is also the investment adviser for the investment company, provided that, among other things, the plan does not pay an investment management, investment advisory or similar fee with respect to the plan

6. The valuation of securities used to purchase shares of the Funds was implemented pursuant to purchase agreements between the Funds and the Bank (the Purchase Agreements). In accordance with the Purchase Agreements, the securities used to purchase shares of the Funds included only cash and securities that had a readily ascertainable market value. The securities were valued at their current market value in accordance with SEC Rule 17a-7(b). Under Rule 17a-7, the

assets invested in such shares for the entire period of such investment.

The Department is expressing no opinion in this proposed exemption regarding whether any of the transactions with the Funds by the Bank Plans or the Client Plans were covered by either PTE 77-3 or PTE 77-4, respectively.

“current market price” for specific types of CIF securities involved in the transactions is determined as follows:

a. If the security is a “reported security” as the term is defined in Rule 11Aa3-1 under the Securities Exchange Act of 1934 (the ‘34 Act), the last sale price with respect to such security reported in the consolidated transaction reporting system (the Consolidated System); or, if there are no reported transactions in the Consolidated System that day, the average of the highest current independent bid and the lowest current independent offer for such security (reported pursuant to Rule 11Ac1-1 under the ‘34 Act), as of the close of business on the CIF valuation date.

b. If the security is not a reported security, and the principal market for such security is an exchange, then the last sale on such exchange or, if there are no reported transactions on such exchange that day, the average of the highest current independent bid and lowest current independent offer on the exchange as of the close of business on the CIF valuation date.

c. If the security is not a reported security and is quoted in the NASDAQ system, then the average of the highest current independent bid and lowest current independent offer reported on Level 1 of NASDAQ as of the close of business on the CIF valuation date.

d. For all other securities, the average of the highest current independent bid and lowest current independent offer determined on the basis of reasonable inquiry from at least three independent sources as of the close of business on the CIF valuation date.

The pricing information required for securities that were either a "reported security" (as defined in SEC Rule 11Aa3-1 under the Securities Exchange Act of 1934) or traded on an exchange or quoted by the NASDAQ system, was obtained from Interactive Data Corporation, a recognized independent pricing service.<sup>8</sup> Securities which were not a "reported security", and were not traded on an exchange or quoted by the NASDAQ system, were priced on the date of the transaction by having the Bank's portfolio managers under the CIFs obtain bid and offer prices from three independent brokers and using the average of the highest independent bid and lowest independent offer price.<sup>9</sup>

The Bank represents that these valuation procedures were applied uniformly for all assets held by the CIFs. A single market value was used for each unit of the same security distributed from the CIFs. For the newly established Funds, the value determined for the assets used to purchase shares of the Funds was also used to determine the net asset value of the Funds and the pro-rated value of the shares issued to the Client Plans purchased with the assets distributed from the CIFs. Immediately following the consummation of the Fund Transactions, the value of the shares of the Funds, as so determined, held by each Client Plan was equal to the value of the assets received by the

Client Plans from the CIFs immediately prior to the consummation of the Fund Transactions.

In connection with the Bank's proposal that assets be used to purchase shares of the Funds, the Bank delivered to an independent fiduciary for each Client Plan with assets invested in a CIF (i.e., a Second Fiduciary) copies of the prospectuses and summaries of supplemental information relating to the Funds. The Second Fiduciary for each Client Plan received a schedule of the rates of all trustee, investment management and other fees charged to the Client Plan by the Bank. Participation in the Fund Transactions by a Plan was conditioned upon receipt of a letter (the Consent Letter) executed by the Second Fiduciary, acknowledging receipt and review of the informational materials and approving the fees to be paid to the Bank by the Funds and the Client Plan.

In the case of Client Plans from which the Bank did not receive Consent Letters, any assets that would otherwise have been distributed by a CIF to such Plans either were retained in the CIF, if the CIF was continuing, or were liquidated and the proceeds invested in other CIFs or in other investments permitted under the terms of the related trust or investment management agreement with the Bank.

No sales commissions, loads or other fees were charged to, or paid by, any Client Plan in connection with the Fund Transactions. In addition, no redemption fees were charged to or paid by any Client Plan for the redemption of any of its shares in the Funds.

7. In consideration of its management of the Funds, SAM received investment advisory fees from the Funds that were computed daily and paid monthly based on the average daily net assets of the Funds. The portion of those fees attributable to a Client Plan were credited to the Client Plan each month as an income item and shown separately on the monthly financial statements prepared for the Client Plan by the Bank. The fees were allocated among the Client Plans invested in the Funds based on the value of the Plan's investment in each Fund, determined daily. Fees for services by the Bank were billed to each Client Plan monthly or quarterly, after the portion of SAM's investment advisory fees allocable to the Client Plan for the month or quarter were credited to the Client Plan. The Bank believes that this fee structure was consistent with the conditions required by PTE 77-4.<sup>10</sup>

<sup>10</sup> Section II(c) of PTE 77-4, in pertinent part, permits the payment of investment advisory fees by

The Bank represents that no fees or other compensation, directly or indirectly, have been received from the Funds, or from The Winsbury Company or its affiliates (Winsbury), other than: (i) The investment advisory fees paid to SAM by the Funds that were credited to the Client Plans as described above, (ii) fees for investment advisory services paid to SAM by the Funds that were based on assets of the Funds that were not attributable to the investment in the Funds by Client Plans, and (iii) fees paid to the Bank for providing administrative services as a shareholder servicing agent, custodian and sub-administrator. In this regard, the Bank has not received any fees payable pursuant to Rule 12b-1 under the 1940 Act in connection with transactions involving any shares of the Funds.

Prior to the subject exemption request, the Bank states that the rates of fees charged to or paid by a Client Plan or the Funds to the Bank in connection with the Client Plan's investment in the Funds were not changed unless an independent fiduciary of the Plan was notified of the change in advance and approved, in writing, the continuation of the Client Plan's investment in the Funds or additional purchases and sales of shares of the Funds.

#### *Future Conversion Transactions*

8. The Bank anticipates that in the future it may engage in transactions like the Fund Transactions. The Bank represents that such transactions will be structured either (i) exactly as the Fund Transactions, with assets being distributed from CIFs to Plans and then used by the Client Plans to purchase shares of the Funds, or (ii) without intermediate distribution to the Client Plans, with assets being transferred in-kind from CIFs to the Funds in exchange for shares of the Funds. In each instance, all or a pro rata portion of the assets of a CIF will be transferred to a Fund in exchange for shares of such Fund.

Prior to any conversion transaction involving a CIF, the Bank will obtain the approval of an independent fiduciary of the Plan (i.e., a Second Fiduciary), who will generally be the Client Plan's named fiduciary, trustee, or sponsoring employer. The Bank will provide the Second Fiduciary with a current

the investment company to a plan fiduciary under the terms of an investment advisory agreement adopted in accordance with section 15 of the 1940 Act. Section II(c) states further that this condition does not preclude payment of an investment advisory fee by the plan to the plan fiduciary based on total plan assets from which a credit has been subtracted representing the plan's pro rata share of investment advisory fees paid by the investment company to such plan fiduciary.

<sup>8</sup> The applicant states that securities held by the CIFs which were priced by Interactive Data Corporation were the type of securities described under SEC Rule 17a-7(b) (1)-(3).

<sup>9</sup> The applicant states that securities held by the CIFs which were priced by the average between the highest bid and lowest offer prices quoted by three independent brokers were securities described under SEC Rule 17a-7(b)(4).

prospectus for each Fund and a written statement giving full disclosure of the fee structure under which investment advisory fees received by the Bank (i.e., SAM) will be credited back to the Plan. The disclosure statement will explain why the Bank believes the investment of assets of the Plan in the Funds is appropriate. The disclosure statement will also describe, as applicable, any limitations on the Bank regarding which plan assets may be invested in shares of the Funds and, if so, the nature of such limitations.

After consideration of such information, the Second Fiduciary may authorize the Bank to invest plan assets in the Funds, to receive fees from the Funds, and to purchase additional shares of the Funds with the fees credited back to the Client Plan by the Bank. The authorization will be terminable at will by the Second Fiduciary, without penalty to the Client Plan, upon receipt by the Bank of written notice of termination.

A form expressly providing an election to terminate the authorization (a "Termination Form"), with instructions on the use of the form, will be supplied to the Second Fiduciary no less than annually. The Termination Form will instruct the Second Fiduciary that the authorization is terminable at will by the Client Plan, without penalty to the Client Plan, upon receipt by the Bank of written notice from the Second Fiduciary, and that failure to return the form will result in the continued authorization of the Bank to engage in the subject transactions on behalf of the Client Plan and to receive fees therefor.

The Termination Form may be used to notify the Bank in writing to effect a termination by selling the shares held by the Client Plan requesting such termination within one business day following receipt by the Bank of the form. If, due to circumstances beyond the Bank's control, the sale cannot be executed within one business day, the Bank will complete the sale within the next business day.

For all in-kind transfers of CIF assets to a Fund following the publication of this proposed exemption in the Federal Register, the Bank will send by regular mail to each affected Client Plan, within 30 days after completion of the transaction, a written confirmation containing:

(i) The identity of each security that was valued for purposes of the transaction in accordance with Rule 17a-7(b)(4);

(ii) The price of each such security involved in the transaction;

(iii) The identity of each pricing service or market-maker consulted in determining the value of such securities.

In addition to the information described above, the Bank will send, within 90 days after completion of each in-kind transfer, a written confirmation containing:

(i) The number of CIF units held by the Client Plan immediately before the transfer, the related per unit value, and the total dollar amount of such CIF units; and

(ii) The number of shares in the Funds that are held by the Client Plan following the transfer, the related per share net asset value, and the total dollar amount of such shares.

The price paid or received by a Client Plan for shares in a Fund will be the net asset value per share at the time of the transaction, as defined in Section IV(e), and will be the same price which would have been paid or received for the shares by any other investor at that time.

#### *Current Fee Arrangement*

9. Effective as of October 1, 1995, the applicant represents that the Bank has implemented a new fee structure (the Fee Structure) for the Client Plans allowing for direct credits to each Client Plan, in the form of cash or additional Fund shares, of such Plan's proportionate share of all investment advisory fees received by the Bank from the Funds. The Bank states that the Fee Structure is at least as advantageous to the Client Plans as an arrangement, as described in PTE 77-4, whereby investment advisory fees paid by the Funds to the Bank are offset against fees paid directly to the Bank by the Client Plans.

Under the Fee Structure, the Bank charges its standard fees to the Client Plans for serving as either a trustee, directed trustee, investment manager, or custodian.<sup>11</sup> These fees are usually billed on a quarterly basis. The annual charges for a Client Plan account are individually negotiated with the Bank based on the Bank's standard fee schedules. The Bank provides investment services to the Client Plans for which it acts as a trustee with investment discretion, including sweep services for uninvested cash balances in

such Plans, under a bundled or single fee arrangement which is calculated as a percentage of the market value of the Plan assets under management. Thus, in such instances, there are no separate charges for the provision of particular services to the Client Plans. However, for Client Plans where investment decisions are directed by a Second Fiduciary, a separate charge is assessed for particular services where the Second Fiduciary specifically agrees to have the Bank provide such services to the Client Plan. With respect to sweep services, the Bank represents that such services are provided at no additional charge where the Bank exercises investment discretion for the Client Plan's assets and, in any event, are provided only if approved by a Second Fiduciary for the Client Plan after disclosure of the services to be provided.<sup>12</sup>

In addition, the Bank (i.e., SAM or some other affiliate as described herein) charges the Funds investment advisory fees in accordance with investment advisory agreements between SAM and the Funds. These agreements have been approved by the independent members of the Board of Directors of the Funds (the Directors) in accordance with the applicable provisions of the 1940 Act, and any changes in the fees will also be approved by the Directors. These fees are paid on a monthly basis by the Funds.

At the beginning of each month, and essentially simultaneously with the payment of the investment advisory fees by the Funds to the Bank (in no event later than the same business day), the Bank credits to each Client Plan its proportionate share of all investment advisory fees charged by the Bank (i.e., SAM or an affiliate) to the Funds, including any investment advisory fees paid by the Bank to third party sub-advisors (referred to hereafter as "the Alternative Credit Program"). The credited fees are used to acquire additional shares of the Funds on behalf of the Client Plan or are returned to the Client Plan's trust account in the form of cash, as directed by the Second Fiduciary.

The Bank retains fees received from the Funds for custody and shareholder services and will retain additional fees received in the future for other secondary services. The Bank states that

<sup>11</sup> The applicant represents that all fees paid by Client Plans directly to the Bank for services performed by the Bank are exempt from the prohibited transaction provisions of the Act by reason of section 408(b)(2) of the Act and the regulations thereunder (see 29 CFR 2550.408b-2). The Department notes that to the extent there are prohibited transactions under the Act as a result of services provided by the Bank directly to the Client Plans which are not covered by section 408(b)(2), no relief is being proposed herein for such transactions.

<sup>12</sup> See DOL Letter dated August 1, 1986 to Robert S. Plotkin, Assistant Director, Division of Banking Supervision and Regulation, Board of Governors of the Federal Reserve System, stating the Department's views regarding the application of the prohibited transaction provisions of the Act to sweep services provided to plans by fiduciary banks and the potential applicability of certain statutory exemptions as described therein.

such secondary services are distinct from the services provided by the Bank as trustee to a Client Plan. Trustee services rendered at the Plan-level include maintaining custody of the assets of the Client Plan (including the Fund shares, but not the assets underlying the Fund shares), processing benefit payments, maintaining participant accounts, valuing plan assets, conducting non-discrimination testing, preparing Forms 5500 and other required filings, and producing statements and reports regarding overall plan and individual participant holdings. These trustee services are necessary regardless of whether the Client Plan's assets are invested in the Funds. Thus, the Bank represents that its proposed receipt of fees for both secondary services at the Fund-level and trustee services at the Plan-level would not involve the receipt of "double fees" for duplicative services to the Client Plans because a Fund is charged for custody and other services relative to the individual securities owned by the Fund, while a Client Plan is charged for the maintenance of Plan accounts reflecting ownership of the Fund shares and other assets.<sup>13</sup>

The Bank represents that for each Client Plan, the combined total of all fees received by the Bank for the provision of services to the Client Plan, and in connection with the provision of services to the Funds in which the Client Plan may invest, will not be in excess of "reasonable compensation" within the meaning of section 408(b)(2) of the Act.<sup>14</sup>

<sup>13</sup> The Department notes that although certain transactions and fee arrangements are the subject of an administrative exemption, a Client Plan fiduciary must still adhere to the general fiduciary responsibility provisions of section 404 of the Act. Thus, the Department cautions the fiduciaries of the Client Plans investing in the Funds that they have an ongoing duty under section 404 of the Act to monitor the services provided to the Client Plans to assure that the fees paid by the Client Plans for such services are reasonable in relation to the value of the services provided. Such responsibilities would include determinations that the services provided are not duplicative and that the fees are reasonable in light of the level of services provided.

The Department also notes that the Bank, as a trustee and investment manager for a Client Plan in connection with the decision to invest Client Plan assets in the Funds, has a fiduciary duty to monitor all fees paid by a Fund to the Bank, its affiliates, and third parties for services provided to the Fund to ensure that the totality of such fees is reasonable and would not involve the payment of any "double" fees for duplicative services to the Fund by such parties.

<sup>14</sup> The Department is providing no opinion in this proposed exemption as to whether the conditions required for exemptive relief under section 408(b)(2) of the Act, and the regulations thereunder (see 29 CFR 2550.408b(2)), would be met for all fees received by the Bank for the provision of services to the Client Plans.

The Bank states that the Alternative Credit Program ensures that the Bank does not receive any investment advisory fees from the Funds as a result of the investment in the Funds by the Client Plans. Thus, the Fee Structure with the Alternative Credit Program essentially has the same effect in crediting the Bank's investment advisory fees received from the Funds as an arrangement allowing for an offset of such fees against investment management fees charged directly to the Client Plans. The Bank prefers the Fee Structure with the Alternative Credit Program because it allows fees for fiduciary services charged at the Plan-level to remain fixed without any adjustments to such fees based on the investment advisory fees paid by the Funds to the Bank.

10. The Bank is responsible for establishing and maintaining a system of internal accounting controls for the crediting of fees under the Alternative Credit Program. In addition, the Bank has retained the services of Ernst & Young LLP (E&Y) in Cleveland, Ohio, an independent accounting firm, to audit annually the crediting of fees to the Client Plans under this program. In this regard, the Bank states that in the future either E&Y or some other qualified independent auditor will be retained by the Bank to perform annual audits of the Alternative Credit Program (the Auditor). Such audits provide independent verification of the proper crediting of such fees to the Client Plans. Information obtained from the audits is used in the preparation of required financial disclosure reports for the Client Plans. In its annual audit of the Alternative Credit Program, the Auditor is required to: (i) review and test compliance with the specific operational controls and procedures established by the Bank for making the credits; (ii) verify on a test basis the daily credit factors transmitted to the Bank by the Funds; (iii) verify on a test basis the proper assignment of credit identification fields to the Client Plans; (iv) verify on a test basis the credits paid in total to the sum of all credits paid to each Client Plan; and (v) recompute the amount of the credits determined for selected Client Plans and certify that the credits were made to the proper Client Plan.

The Bank will correct any error identified either by the internal audit by the Bank or by the independent auditor. With respect to any shortfall in credited fees to a Client Plan involving cash credits, the Bank will make a cash payment to the Client Plan equal to the amount of the error plus interest paid at money market rates offered by the Bank

for the period involved. With respect to any shortfall in credited fees involving a Client Plan where the Second Fiduciary's election was to have credited fees invested in shares of the Funds, the Bank will make a cash payment equal to the amount of the error plus interest based on the rate of return for shares of the Fund that would have been acquired. Any excess credits made to a Client Plan will be corrected by an appropriate deduction and reallocation of cash during the next payment period to reflect accurately the amount of total credits due to the Client Plan for the period involved.

11. As discussed above, the Bank currently acts as a custodian, sub-administrator, and/or shareholder servicing agent for the Funds, and anticipates providing additional "secondary services" to the Funds in the future. In this regard, the Bank represents that certain of the Funds may institute a securities lending program (the Program) which will be administered by SAM or another affiliate of the Bank. SAM, as the investment adviser for the Fund, would be responsible for negotiating the terms of the loans, selecting borrowers, and investing cash collateral. SAM would receive an additional fee for its services to the Fund in connection with the Program, subject to the supervision and approval of the Directors. The Bank, under a separate agreement or an amendment to the current custody agreement with the Fund, would agree to provide additional custodial and administrative tasks associated with the Program. The Fund would pay the Bank a fee based on the number and complexity of the tasks the Bank is required to perform in connection with the Program, that would take into account the responsibilities and expenses incurred by the Bank. As custodian for the Fund under the Program, the Bank would perform the following tasks: (i) deliver loaned securities from the Fund to borrowers; (ii) arrange for the return of loaned securities to the Fund at the termination of the loans; (iii) monitor daily the value of the loaned securities and collateral; (iv) request that borrowers add to the collateral when required by the loan agreement; and (v) provide recordkeeping and accounting services necessary for the operation of the Program. The Bank proposes to charge fees for its services to the Funds under the Program no sooner than 30 days following the issuance of a notice and Termination Form to the Second Fiduciary of each of the Client Plans invested in the participating Funds.



The Bank represents that the terms of any securities loan under the Program would comply with the conditions required for an exemption under PTE 81-6, 46 FR 7527 (January 23, 1981) as amended (see 52 FR 18754, May 19, 1987), as though the participating Fund were an employee benefit plan subject to such conditions.<sup>15</sup>

Therefore, the Bank believes that the interests of the Client Plans, as Fund investors, will be protected under the Program. The Bank notes that the SEC issued on May 25, 1995, a "no-action" letter in connection with the Program.

12. With respect to the receipt of fees by the Bank from a Fund in connection with any Client Plan's investment in the Fund, the Bank states that a Second Fiduciary receives full and detailed written disclosure of information concerning the Fund in advance of any investment by the Client Plan in the Fund. On the basis of such information, the Second Fiduciary authorizes in writing the investment of assets of the Client Plan in the Fund and the fees to be paid by the Fund to the Bank. In addition, the Bank represents that the Second Fiduciary of each Client Plan invested in a particular Fund will receive full written disclosure, in a statement separate from the Fund prospectus, of any proposed increases in the rates of fees charged by the Bank to the Funds for secondary services, which are above the rate reflected in the prospectus for the Fund, at least 30 days prior to the effective date of such increase. In the event that the Bank provides an additional secondary service to a Fund for which a fee is charged or there is an increase in the amount of fees paid by the Funds to the Bank for any secondary services, resulting from a decrease in the number or kind of services performed by the Bank for such fees in connection with a previously authorized secondary

service, the Bank will, at least thirty days in advance of the implementation of such additional service or fee increase, provide written notice to the Second Fiduciary explaining the nature and the amount of the additional service for which a fee will be charged or the nature and amount of the increase in fees of the affected Fund.<sup>16</sup> Such notice will be made separate from the Fund prospectus and will be accompanied by a Termination Form. The Second Fiduciary will also receive full written disclosure in a Fund prospectus or otherwise of any increases in the rate of fees charged by the Bank to the Funds for investment advisory services even though such fees will be credited, as required by Section II(d) above.

Any authorizations by a Second Fiduciary regarding the investment of a Client Plan's assets in a Fund and the fees to be paid to the Bank, including any future increases in rates of fees for secondary services, are or will be terminable at will by the Second Fiduciary, without penalty to the Client Plan, upon receipt by the Bank of written notice of termination. The Bank states that a Termination Form expressly providing an election to terminate the authorization with instructions on the use of the form is supplied to the Second Fiduciary no less than annually. The instructions for the Termination Form include the following information:

(a) The authorization is terminable at will by the Client Plan, without penalty to the Client Plan, upon receipt by the Bank of written notice from the Second Fiduciary; and

(b) Failure to return the form will result in continued authorization of the Bank to engage in the subject transactions on behalf of the Client Plan.

The Termination Form may be used to notify the Bank in writing to effect a termination by selling the shares of the Funds held by the Client Plan requesting such termination within one business day following receipt by the

Bank of the form. The Bank states that if, due to circumstances beyond the control of the Bank, the sale cannot be executed within one business day, the Bank will complete the sale within the next business day.

Any disclosure of information regarding a proposed increase in the rate of any fees for secondary services will be accompanied by an additional Termination Form with instructions on the use of the form as described above. Therefore, the Second Fiduciary will have prior notice of the proposed increase and an opportunity to withdraw from the Funds in advance of the date the increase becomes effective. Although the Second Fiduciary will also have notice of any increase in the rates of fees charged by the Bank to the Funds for investment advisory services, through an updated prospectus or otherwise, such notice will not be accompanied by a Termination Form since all increases in investment advisory fees will be credited by the Bank to the Client Plans and will be subject to an annual reauthorization as described above. However, if the Termination Form has been provided to the Second Fiduciary for the authorization of a fee increase, then a Termination Form for an annual reauthorization will not be provided by the Bank for that year unless at least six months has elapsed since the Termination Form was provided for the fee increase.

The Bank states that the Second Fiduciary always receives a current prospectus for each Fund and a written statement giving full disclosure of the Fee Structure prior to any investment in the Funds. The disclosure statement explains why the Bank believes that the investment of assets of the Client Plan in the Funds is appropriate. The disclosure statement also describes whether there are any limitations on the Bank with respect to which Client Plan assets may be invested in shares of the Funds and, if so, the nature of such limitations.<sup>17</sup>

The Bank states further that the Second Fiduciary receives an updated prospectus for each Fund at least annually and either annual or semi-annual financial reports for each Fund, which include information on the

<sup>15</sup> PTE 81-6, as amended, permits the lending of securities that are assets of an employee benefit plan to a broker-dealer registered under the Securities Exchange Act of 1934 (the 1934 Act) or exempted from registration under section 15(a)(1) of the 1934 Act as a dealer in exempted Government securities (as defined in section 3(a)(12) of the 1934 Act) or to a bank. The conditions of PTE 81-6 require, among other things, that the plan receive from the borrower (either by physical delivery or by book entry in a securities depository) by the close of the lending fiduciary's business on the day in which the securities lent are delivered to the borrower, collateral consisting of cash, securities issued or guaranteed by the U.S. Government or its agencies or instrumentalities, or irrevocable bank letters of credit issued by a person other than the borrower or an affiliate thereof, or any combination thereof, having, as of the close of business on the preceding business day, a market value or in the case of letters of credit a stated amount, equal to not less than 100 percent of the then market value of the securities lent.

<sup>16</sup> With respect to increases in fees, the Department notes that an increase in the amount of a fee for an existing secondary service (other than through an increase in the value of the underlying assets in the Funds) or the imposition of a fee for a newly-established secondary service shall be considered an increase in the rate of such fees. However, in the event a secondary service fee has already been described in writing to the Second Fiduciary and the Second Fiduciary has provided authorization for the fee, and such fee was temporarily waived, no further action by the Bank would be required in order for the Bank to receive such fee at a later time. Thus, for example, no further disclosure would be necessary if the Bank had received authorization for a fee for custodial services from Plan investors and subsequently determined to waive the fee for a period of time in order to attract new investors but later charged the fee.

<sup>17</sup> See section II(d) of PTE 77-4 which requires, in pertinent part, that an independent plan fiduciary receive a current prospectus issued by the investment company and a full and detailed written disclosure of the investment advisory and other fees charged to or paid by the plan and the investment company, including a discussion of whether there are any limitations on the fiduciary/investment adviser with respect to which plan assets may be invested in shares of the investment company and, if so, the nature of such limitations.



Auditor's findings as to the proper crediting of the investment advisory fees by the Bank to the Client Plan. The Bank also provides monthly reports to the Second Fiduciary of all transactions engaged in by the Client Plan, including purchases and sales of Fund shares.

13. No sales commissions are paid by the Client Plans in connection with the purchase or sale of shares of the Funds. In addition, no redemption fees are paid in connection with the sale of shares by the Client Plans to the Funds. The applicant states that the Bank does not, and will not in the future, receive any fees payable pursuant to Rule 12b-1 under the 1940 Act in connection with the transactions. The applicant states further that all other dealings between the Client Plans and the Funds, the Bank or any affiliate, are on a basis no less favorable to the Client Plans than such dealings are with the other shareholders of the Funds.

14. In summary, the applicant represents that the transactions described herein satisfy the statutory criteria of section 408(a) of the Act and section 4975(c)(2) of the Code because: (a) the Funds provide the Client Plans with a more effective investment vehicle than collective investment funds maintained by the Bank without any increase in investment management, advisory or similar fees paid to the Bank; (b) the Bank requires annual audits by an independent accounting firm to verify the proper crediting to the Client Plans of investment advisory fees charged by the Bank to the Funds; (c) with respect to any investments in a Fund by the Client Plans and the payment of any fees by the Fund to the Bank, a Second Fiduciary receives full written disclosure of information concerning the Fund, including a current prospectus and a statement describing the Fee Structure, and authorizes in writing the investment of the Client Plan's assets in the Fund and the fees paid by the Fund to the Bank; (d) any authorizations made by a Client Plan regarding investments in a Fund and fees paid to the Bank, or any increases in the rates of fees for secondary services which are retained by the Bank, are or will be terminable at will by the Client Plan, without penalty to the Client Plan, upon receipt by the Bank of written notice of termination from the Second Fiduciary; (e) no commissions or redemption fees are paid by the Client Plan in connection with either the acquisition of Fund shares or the sale of Fund shares; (f) the Bank does not receive any fees payable pursuant to Rule 12b-1 under the 1940 Act in connection with the transactions; (g) the in-kind transfers

of CIF assets into the Funds are done with the prior written approval of independent fiduciaries (i.e. the Second Fiduciary) following full and detailed written disclosure concerning the Funds; (h) each Client Plan receives shares of a Fund which have a total net asset value that is equal to the value of the Client Plan's pro rata share of the assets of the CIF on the date of the in-kind transfer, based on the current market value of the CIF's assets as determined in a single valuation performed in the same manner at the close of the same business day in accordance with independent sources and the procedures established by the Funds for the valuation of such assets; and (i) all dealings between the Client Plans, the Funds and the Bank, are on a basis which is at least as favorable to the Client Plans as such dealings are with other shareholders of the Funds.

#### Notice to Interested Persons

Notice of the proposed exemption shall be given to all Second Fiduciaries of Client Plans described herein that had investments in a terminating CIF and from whom approval was sought, or will be sought prior to the granting of this proposed exemption, for a transfer of a Client Plan's CIF assets to a Fund. In addition, interested persons shall include the Second Fiduciaries of all Client Plans which are currently invested in the Funds, as of the date the notice of the proposed exemption is published in the Federal Register, where the Bank provides services to the Funds and received fees which would be covered by the exemption, if granted.

Notice to interested persons shall be provided by first class mail within fifteen (15) days following the publication of the proposed exemption in the Federal Register. Such notice shall include a copy of the notice of proposed exemption as published in the Federal Register and a supplemental statement (see 29 CFR 2570.43(b)(2)) which informs all interested persons of their right to comment on and/or request a hearing with respect to the proposed exemption. Comments and requests for a public hearing are due within forty-five (45) days following the publication of the proposed exemption in the Federal Register.

**FOR FURTHER INFORMATION CONTACT:** Mr. E. F. Williams of the Department, telephone (202) 219-8194. (This is not a toll-free number.)

Zausner Foods Corp. Savings Plus Plan (the Plan); Located in New Holland, Pennsylvania; Proposed Exemption

[Application No. D-10064]

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted, the restrictions of section 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the past sale by the Plan of certain units of limited partnership interests (the Units) to Zausner Foods Corp. (Zausner Foods), a party in interest with respect to the Plan, provided that the following conditions were satisfied: (1) the sale was a one-time transaction for cash; (2) the Plan paid no commissions nor other expenses relating to the sale; and (3) the purchase price was the greater of: (a) the fair market value of the Units as determined by a qualified, independent appraiser, or (b) the original acquisition cost of the Units plus attributable opportunity costs.

**EFFECTIVE DATE:** The proposed exemption, if granted, will be effective as of December 29, 1995.

#### Summary of Facts and Representations

1. The Plan is a profit sharing plan sponsored by Zausner Foods. Zausner Foods is a member of a controlled group of corporations that manufactures and sells various food products, including milk-related products. As of December 31, 1994, the Plan had 1,021 participants and total assets of approximately \$12,256,538. Prior to January 1, 1996, Charles Schwab Trust Co. served as the Plan trustee. Effective January 1, 1996, Dreyfus Trust Co. became the Plan trustee.

2. Among the assets of the Plan were the Units, which were 64 shares of the MLH Income Realty Partnership V (the Partnership). The Partnership was formed as of December 31, 1983 for purposes of investing in commercial, industrial, and residential real estate. The Plan acquired the Units in 1991 when the AltaDena Certified Dairy (AltaDena) Savings & Investment Plan (the AltaDena Plan) was merged into, and survived by, the Plan. The AltaDena Plan, on the recommendation of an investment counselor at Merrill Lynch, acquired at various public offerings in 1985 a total of 70 Units at a cost of \$1,000 per Unit. When the Plan and the

AltaDena Plan were merged in 1991, the two owners of AltaDena, who were also AltaDena Plan participants, received a total of six of the Units as an in-kind distribution upon the termination of their employment. At the time of the merger, the Plan's trustees froze the investment in the Partnership by not permitting participants to invest in it. The applicant represents that neither Zausner Foods, AltaDena, nor any of their respective officers or directors separately invested in the Partnership and that the other investors in the Units are unrelated third parties. The Partnership had made cash distributions with respect to the 64 Units in the cumulative amount of \$43,042.56 (\$672.54 per Unit), through November 13, 1995.

The Partnership originally intended to lease the properties for a period of six to ten years from the date of the Partnership's formation, then sell off the appreciated properties at a gain. Investors were to receive yearly cash distributions derived from the rental properties and from the sale proceeds of the properties as they were liquidated. However, due to subsequent adverse conditions in the real estate market and the economy in general, the Partnership has been unable to sell a number of the properties for a profit. The Partnership has therefore altered its plans and continues to hold these properties.

3. The applicant represents that the Units are a highly illiquid investment for which there is a very limited secondary market.<sup>18</sup> Merrill Lynch provides a service to assist clients wishing to buy and sell Partnership Units. The applicant represents that at the time the Plan and the AltaDena Plan were merged in 1991, the Plan's trustees contacted Merrill Lynch in order to discuss a possible sale of the remaining 64 Units but were told that there was no interest in the investments. Recently, Joseph E. Lundy, Vice President at Merrill Lynch's Lancaster, Pennsylvania office, advised the applicant that there was no market for the Units, that no market was likely to develop in the foreseeable future, and that if a purchaser for the Units were to be found, the price obtained would be approximately \$350-\$390 per Unit, less than one-half the original cost of the investment.

The applicant also obtained an independent appraisal of the Units from Jack L. Hess, CPA, of Hess & Hess, Certified Public Accountants, located in

Lancaster, Pennsylvania. After reviewing the pertinent data, Mr. Hess estimated that the Units' fair market value as of May 9, 1995 was \$450 per Unit. Mr. Hess also noted that, as of December 31, 1994, the Units had a net asset value of \$535 per Unit, a figure which is provided to Merrill Lynch by an independent valuation service on an annual basis. The appraisal states that the Partnership, which has been liquidating its holdings, expects to sell its remaining properties over the next two years. Provided that the Partnership sells its remaining properties during that period, investors may expect to receive approximately \$500 per Unit in final cash distributions over the next two years. The value of the Units on the secondary market, estimated at \$450 per Unit, reflects the present value of this expected benefit, as well as a trading discount.

4. On December 29, 1995, Zausner Foods purchased the Units from the Plan for \$55,118.72, which was allocated on a pro rata basis among the participants' accounts that had invested in the Units. This amount represents the greater of: (a) the fair market value of the Units as determined by a qualified, independent appraiser, or (b) the Units' original acquisition cost to the AltaDena Plan plus opportunity costs attributable to the Units. Because the fair market value of the Units was less than their acquisition cost, Zausner Foods purchased the Units from the Plan for the latter amount. Taking into account the purchase price (\$55,118.72) and all cash distributions (\$43,042.56), the Plan received a rate of return on the Units' acquisition cost (\$64,000) slightly in excess of five percent for each of the ten years that the Plan (and its predecessor) had held the Units. The sale was a one-time transaction for cash, and the Plan paid no commissions nor other expenses relating to the sale.

The applicant represents that the subject transaction was in the interests of the Plan because if the Plan had attempted a sale of the Units on the open market, the Plan would have received substantially less than the amount the applicant was willing to pay. In addition, the sale converted the Units into liquid assets that are now available for any required distributions, as well as being subject to professional management.

5. In summary, the applicant represents that the subject transaction satisfied the statutory criteria for an exemption under section 408(a) of the Act for the following reasons: (1) the sale was a one-time transaction for cash; (2) the Plan paid no commissions nor other expenses relating to the sale; (3)

the sale enhanced the liquidity of the assets of the Plan; and (4) the purchase price was the greater of: (a) the fair market value of the Units as determined by a qualified, independent appraiser, or (b) the original acquisition cost of the Units plus attributable opportunity costs.

#### Tax Consequences of Transaction

The Department of the Treasury has determined that if a transaction between a qualified employee benefit plan and its sponsoring employer (or affiliate thereof) results in the plan either paying less than or receiving more than fair market value, such excess may be considered to be a contribution by the sponsoring employer to the plan and therefore must be examined under applicable provisions of the Code, including sections 401(a)(4), 404 and 415.

#### Notice to Interested Persons

Notice of the proposed exemption shall be given to all interested persons by personal delivery and by first-class mail within 10 days of the date of publication of the notice of pendency in the Federal Register. Such notice shall include a copy of the notice of proposed exemption as published in the Federal Register and shall inform interested persons of their right to comment and/or to request a hearing with respect to the proposed exemption. Comments and requests for a hearing are due within 40 days of the date of publication of this notice in the Federal Register.

#### FOR FURTHER INFORMATION CONTACT:

Karin Weng of the Department, telephone (202) 219-8881. (This is not a toll-free number.)

IRA Rollover FBO John W. Meisenbach (the IRA); Located in Seattle, Washington; Proposed Exemption

[Application No. D-10114]

The Department is considering granting an exemption under the authority of section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted, the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the proposed sale by the IRA of certain stock (the Stock) to John W. Meisenbach, a disqualified person with respect to the IRA, provided that the following conditions are satisfied: (a) the sale is a one-time transaction for cash; (b) the IRA pays no commissions nor other expenses relating to the sale; and (c) the purchase price is the fair

<sup>18</sup> The Department expresses no opinion herein on whether the acquisition and holding of the Units by the Plan violated any of the provisions of Part 4 of Title I in the Act.

market value of the Stock as determined by a qualified, independent appraiser as of the date of the sale.<sup>19</sup>

#### Summary of Facts and Representations

1. The IRA is an individual retirement account, as described under section 408(a) of the Code. The IRA was established by John W. Meisenbach, who is the sole participant. As of July 28, 1995, the IRA had total assets of approximately \$7,691,680.45. The trustee of the IRA is the Delaware Charter Guarantee & Trust Company.

2. Among the assets of the IRA are 422,265 shares of closely-held Stock in Garden Botanika, Inc. (Garden Botanika), which markets cosmetic and personal care products featuring natural and herbal ingredients via a chain of company-owned specialty retail stores. The applicant represents that the IRA acquired most of the Stock from the issuer, as well as 40,000 shares from a private individual, at various times and at various prices during the period from September 9, 1993 to January 1, 1995. An IRA account statement dated July 28, 1995 lists the Stock as having an aggregate fair market value of \$677,262.50.<sup>20</sup> The applicant represents that the total acquisition cost of the Stock was less than or equal to that amount.

3. The applicant has obtained an independent appraisal of the Stock from Dennis H. Locke, CFA, ASA, of Management Advisory Service, located in Seattle, Washington. Relying on the discounted cash flow method of valuing a business enterprise, Mr. Locke estimated that the Stock's fair market value as of August 31, 1995 was \$2.10 per share (or a total of \$886,756.50), based on 33,822,315 diluted shares outstanding. Mr. Locke stated that his appraisal takes into account future expectations for the performance of Garden Botanika and for business and market conditions in general, as well as a 10% discount to reflect the Stock's limited marketability.

4. Mr. Meisenbach proposes to purchase the Stock from his own IRA for the fair market value of the Stock as of the date of the sale, based on an updated independent appraisal. In light of the extreme volatility of non-publicly traded stocks, Mr. Meisenbach desires to

divest the IRA of the Stock so as to protect the IRA's current asset value, create liquidity, and provide for his long-term security. The applicant, who is now 59 years of age, intends to receive distributions from the IRA soon after attaining age 59½. The sale will be a one-time transaction for cash, and the IRA will pay no commissions nor other expenses relating to the sale.

The applicant represents that the likelihood of selling such a large block of the Stock at its appraised value to an unrelated third party is questionable, due to the limited marketability of the Stock. In addition, the applicant represents that the proposed transaction is in the interests of the IRA because the sale will reduce the risk of large losses in the IRA, as well as the administrative burdens involved in valuing the IRA assets.

5. In summary, the applicant represents that the proposed transaction satisfies the statutory criteria for an exemption under section 4975(c)(2) of the Code for the following reasons: (a) the sale will be a one-time transaction for cash; (b) the IRA will pay no commissions nor other expenses relating to the sale; (c) the sale will enhance the liquidity and protect the current value of the IRA assets; (d) the purchase price will be the fair market value of the Stock as determined by a qualified, independent appraiser as of the date of the sale; and (e) Mr. Meisenbach is the only participant who will be affected by the proposed transaction.

#### Notice to Interested Persons

Because Mr. Meisenbach is the sole participant in his IRA, it has been determined that there is no need to distribute the notice of proposed exemption to interested persons. Comments and requests for a hearing with respect to the proposed exemption are due within 30 days of the date of publication of this notice in the Federal Register.

#### FOR FURTHER INFORMATION CONTACT:

Karin Weng of the Department, telephone (202) 219-8881. (This is not a toll-free number.)

Floral Glass and Mirror, Inc. Profit Sharing Plan and Trust (the Plan); Located in Hauppauge, New York; Proposed Exemption

[Application No. D-10144]

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55

FR 32836, 32847, August 10, 1990). If the exemption is granted, the restrictions of sections 406(a), 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the proposed sale of 20 shares of stock of Floral Glass Industries, Inc. (FGI) by the Plan to Mr. Charles Kaplanek, Jr. (Kaplanek), a party in interest with respect to the Plan, provided the following conditions are satisfied: (a) the sale is a one-time transaction for cash; (b) the Plan pays no commissions or other expenses in connection with the transaction; (c) the Plan will receive the fair market value of the shares as determined by a qualified, independent appraiser; and (d) all terms and conditions of the sale will be at least as favorable to the Plan as those obtainable in an arm's-length transaction with an unrelated party at the time of the sale.

#### Summary of Facts and Representations

1. The Plan is sponsored by Floral Glass and Mirror, Inc. (the Employer), a New York corporation. The Plan is a profit sharing plan that permits participants to direct the investment of the assets in their accounts. Participants who do not wish to direct the investments of their own accounts may, instead, have their accounts invested by the Plan trustees. The Plan has 29 participants and beneficiaries, and had assets of \$3,203,599 as of March 31, 1995.

2. Kaplanek is an 80% shareholder of the Employer and is also a trustee of the Plan and a participant in the Plan. On January 1, 1981, Kaplanek's individual account (the Account) in the Plan purchased, at Kaplanek's direction, 20 shares of stock in FGI, a Connecticut corporation with its principal place of business in Cheshire, Connecticut. The 20 shares represented 100% of the outstanding shares of FGI. The purchase price of the Stock was \$20,000, and the Stock was acquired from FGI.

3. The Account still owns the 20 shares, or 100% of the shares of FGI.<sup>21</sup> In addition, Kaplanek is 100% owner of two related corporations, Shapes and Services Limited of Bohemia, New York, and Floral Glass Industries, Inc. of East Rutherford, New Jersey, as well as 80%

<sup>19</sup> Pursuant to 29 CFR 2510.3-2(d), the IRA is not within the jurisdiction of Title I of the Act. However, there is jurisdiction under Title II of the Act pursuant to section 4975 of the Code.

<sup>20</sup> The Department notes the applicant's representation that due to the limited marketability of non-publicly traded stocks, the value of the Stock is difficult to establish, and, therefore, the Stock's value appearing on the IRA account statement dated July 28, 1995 represents an approximation of its fair market value.

<sup>21</sup> The Department notes that under section 2510.3-101(h)(3) of the plan asset regulations, it appears that the Plan's assets include the stock of FGI and all of the underlying assets of FGI. In this regard, the applicant has not asked for relief concerning the operation of FGI, nor is the Department proposing any such relief herein.

owner of the Employer (collectively, the Corporations).

4. The Corporations intend to undergo a reorganization pursuant to which they will be consolidated and/or reorganized into a single corporation. As part of this reorganization, the 20 shares of FGI would be exchanged for shares in the surviving or reorganized corporation. Rather than leaving the 20 shares of FGI in the Plan, Kaplanek instead proposes to purchase the shares from the Account prior to the reorganization.<sup>22</sup>

5. FGI is a manufacturer of insulated glass. In addition, it cuts to size other glass and mirror products and distributes them to the New England region. FGI's products include several items which are registered or bear trademarks. Mr. Martin P. Randisi, President of Rand Consulting Group, Inc., an independent business evaluation and appraisal firm located in Smithtown, New York, has appraised the shares of FGI. Mr. Randisi is a member of the American Society of Appraisers and the American Institute of Certified Public Accountants. Mr. Randisi has represented that he has performed over 1,000 valuations of closely held companies since 1982. Mr. Randisi represents that both he and his firm are independent of, and unrelated to, the Employer and FGI. Mr. Randisi has concluded that as of March 31, 1995, the 20 shares of FGI stock had a value of \$953,000.

6. In summary, the applicant represents that the proposed transaction satisfies the criteria contained in section 408(a) of the Act because: (a) the sale will be a one-time transaction for cash; (b) the Plan will not be required to pay any commissions, fees or other expenses in connection with the sale; (c) the Plan will receive as sales price for the shares the fair market value of the shares as determined by a qualified, independent appraiser; (d) all terms and conditions of the sale will be at least as favorable to the Plan as those obtainable in an arm's-length transaction with an unrelated party; and (e) Kaplanek's Account in the Plan is the only account to be affected by the transaction, and Kaplanek has determined that the transaction is appropriate for his Account and has determined that the transaction should be consummated.

**NOTICE TO INTERESTED PERSONS:** Since Kaplanek is the only Plan participant to be affected by the proposed transaction, the Department has determined that

there is no need to distribute the notice of proposed exemption to interested persons. Comments and requests for a hearing are due within 30 days from the date of publication of this notice of proposed exemption in the Federal Register.

**FOR FURTHER INFORMATION CONTACT:** Gary H. Lefkowitz of the Department, telephone (202) 219-8881. (This is not a toll-free number.)

Coin Acceptors, Inc. Savings and Protection Plan (the Plan); Located in St. Louis, Missouri; Proposed Exemption

[Application No. D-10183]

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted, the restrictions of section 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the past sale by the Plan of certain publicly traded securities (the Securities) to Coin Acceptors, Inc. (Coin Acceptors), a party in interest with respect to the Plan, provided that the following conditions were satisfied: (1) the sale was a one-time transaction for cash; (2) the Plan paid no commissions nor other expenses relating to the sale; (3) the purchase price was the aggregate fair market value of the Securities as of the date of the sale, as determined by the Plan's independent investment manager by reference to the closing prices for the Securities on the New York Stock Exchange (NYSE); and (4) the terms of the sale were at least as favorable to the Plan as those obtainable in an arm's length transaction with an unrelated party.

**EFFECTIVE DATE:** The proposed exemption, if granted, will be effective as of September 29, 1995.

#### Summary of Facts and Representations

1. The Plan is a profit sharing plan with a 401(k) feature sponsored by Coin Acceptors. Coin Acceptors is engaged in the business of manufacturing coin and currency handling devices for use in vending machines. As of September 29, 1995 the Plan had approximately 1,000 participants and total assets of approximately \$10,000,000. Effective September 29, 1995, the Mercantile Bank of St. Louis, N.A. became the Plan trustee.

2. Among the assets of the Plan were the Securities, which were 14 publicly traded securities originally purchased by the Plan on the open market. These 14 Securities were: Actava Group, Bristol Myers Squibb Co., Citicorp, Exide Corp., Grace WR & Co., MBIA, Inc., MGIC Investment Corp., Mercantile Bancorp, Inc., Merry Land & Investment Co., Pep Boys Manny Moe & Jack, Sun Microsystems, Inc., Sysco Corp., United HealthCare Corp., and Verifone, Inc. On September 29, 1995, Coin Acceptors purchased the Securities from the Plan for a total of \$998,519. The Plan realized, in the aggregate, a gain of approximately \$243,737 as a result of the sale.

The applicant represents that all the Plan's assets were being liquidated at that time in connection with a modification to the Plan. Effective October 1, 1995, the Plan permitted participants to direct the investment of their respective individual accounts among six mutual funds. Coin Acceptors, which maintains its own investment portfolio, was interested in purchasing 14 of the Plan's securities which were to be liquidated. The applicant represents that the purchase price of \$998,519 was the aggregate fair market value of the Securities as of the date of the sale. The fair market value of the Securities was determined by Pin Oak Capital, Ltd., one of the Plan's independent investment managers, by reference to the closing prices of the Securities on the NYSE on September 28, 1995 quoted in the *Wall Street Journal* on September 29, 1995, the date of the sale. The applicant maintains, therefore, that the terms of the sale were at least as favorable to the Plan as those obtainable in an arm's length transaction with an unrelated party. The sale was a one-time transaction for cash, and the Plan paid no commissions nor other expenses relating to the sale. Further, the costs of this exemption application will be borne by the applicant.

The applicant represents that selling the Securities to Coin Acceptors, in lieu of selling them on the open market, was in the interests of the Plan because it saved the Plan brokerage commissions totalling at least \$1,458 (based on a commission of \$0.06 per share). In addition, the Plan had the use of the sale proceeds two business days earlier than if the Plan had sold the Securities on the open market through a broker.

The applicant represents they were not aware that the sale would constitute a violation of the prohibited transaction provisions of the Act until October 24, 1995, when the applicant's accountants conducted the annual audit of the Plan.

<sup>22</sup> The applicant represents that FGI is not a Plan sponsor or a contributing employer to the Plan, and that the stock of FGI does not constitute "qualifying employer securities" within the meaning of section 407(d)(5) of the Act.

Outside legal counsel was then consulted, and it was recommended that Coin Acceptors file an application for a retroactive exemption.

5. In summary, the applicant represents that the subject transaction satisfied the statutory criteria for an exemption under section 408(a) of the Act for the following reasons: (1) the sale was a one-time transaction for cash; (2) the Plan paid no commissions nor other expenses relating to the sale; (3) the purchase price was the aggregate fair market value of the Securities as of the date of the sale, as determined by the Plan's independent investment manager by reference to the closing prices for the Securities on the NYSE; and (4) the terms of the sale were at least as favorable to the Plan as those obtainable in an arm's length transaction with an unrelated party.

#### Notice to Interested Persons

Notice of the proposed exemption shall be given to all interested persons by personal delivery and by first-class mail within 15 days of the date of publication of the notice of pendency in the Federal Register. Such notice shall include a copy of the notice of proposed exemption as published in the Federal Register and shall inform interested persons of their right to comment and/or to request a hearing with respect to the proposed exemption. Comments and requests for a hearing are due within 45 days of the date of publication of this notice in the Federal Register.

**FOR FURTHER INFORMATION CONTACT:** Ms. Karin Weng of the Department, telephone (202) 219-8881. (This is not a toll-free number.)

#### General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest of disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(b) of the act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the

employees of the employer maintaining the plan and their beneficiaries;

(2) Before an exemption may be granted under section 408(a) of the Act and/or section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries and protective of the rights of participants and beneficiaries of the plan;

(3) The proposed exemptions, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(4) The proposed exemptions, if granted, will be subject to the express condition that the material facts and representations contained in each application are true and complete and accurately describe all material terms of the transaction which is the subject of the exemption. In the case of continuing exemption transactions, if any of the material facts or representations described in the application change after the exemption is granted, the exemption will cease to apply as of the date of such change. In the event of any such change, application for a new exemption may be made to the Department.

Signed at Washington, DC, this 28th day of February, 1996.

Ivan Strasfeld,

*Director of Exemption Determinations,  
Pension and Welfare Benefits Administration,  
U.S. Department of Labor.*

[FR Doc. 96-5022 Filed 3-4-96; 8:45 am]

BILLING CODE 4510-29-P

### NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 96-019]

#### Notice of Prospective Patent License

**AGENCY:** National Aeronautics and Space Administration.

**SUMMARY:** NASA hereby gives notice that 3M Company of St. Paul, Minnesota 55144-1000, has requested an exclusive license to practice the invention protected by a U.S. Patent Application entitled "Anti-Icing or De-Icing Fluid," NASA Cast No. ARC-12,069-2, which was filed in the U.S. Patent and Trademark Office on January 24, 1996, and assigned to the United States of America as represented by the

Administrator of the National Aeronautics and Space Administration. Written objections to the prospective grant of a license should be sent to Mr. Ken Warsh, Patent Counsel, Ames Research Center.

**DATES:** Responses to this Notice must be received by (insert 60 days from the date of publication in the in the Federal Register).

**FOR FURTHER INFORMATION CONTACT:** Mr. Ken Warsh, Patent Counsel, Ames Research Center, Mail Code 202A-3, Moffett Field, CA 94035; telephone (415) 604-1592.

Dated: February 26, 1996.

Edward A. Frankle,

*General Counsel.*

[FR Doc. 96-4990 Filed 3-4-96; 8:45 am]

BILLING CODE 7510-10-M

[Notice 96-023]

#### Notice of Prospective Patent License

**AGENCY:** National Aeronautics and Space Administration.

**ACTION:** Notice of Prospective Patent License.

**SUMMARY:** NASA hereby gives notice that Air Products and Chemicals, Inc. of Allentown, Pennsylvania has requested an exclusive license to practice the invention described and claimed in a pending U.S. Patent application, entitled "Two-Phase Quality/Flow Meter," NASA Case Number KSC-11725, which is assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. Written objections to the prospective grant of a license to Air Products and Chemicals, Inc. should be sent to Ms. Beth Vrioni, Patent Attorney, John F. Kennedy Space Center.

**DATES:** Responses to this Notice must be received on or before May 6, 1996.

**FOR FURTHER INFORMATION CONTACT:** Ms. Beth A. Vrioni, John F. Kennedy Space Center, Mail Code: DE-TPO, Kennedy Space Center, FL 32899; telephone (407) 867-2544.

Dated: February 26, 1996.

Edward A. Frankle,

*General Counsel.*

[FR Doc. 96-4986 Filed 3-4-96; 8:45 am]

BILLING CODE 7510-01-M

[Notice 96-021]

#### Notice of Prospective Patent License

**AGENCY:** National Aeronautics and Space Administration.

**ACTION:** Notice of Prospective Patent License.

**SUMMARY:** NASA hereby gives notice that Aqua-Terra-Aqua Technologies Corporation of 1240 Valley Belt Road, Cleveland, Ohio 44131, has applied for a partially exclusive license to practice the invention described and claimed in U.S. Patent No. 5,373,110, entitled "Ion Exchange Polymer and Method of Making," which is assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. The field of use will be limited to removal of heavy metals from industrial waste water. Written objections to the prospective grant of a license to Aqua-Terra-Aqua Technologies Corporation should be sent to Mr. Kent Stone.

**DATES:** Responses to this Notice must be received by (insert 60 days from date of publication in the Federal Register).

**FOR FURTHER INFORMATION CONTACT:** Mr. Kent Stone, Patent Attorney, NASA Lewis Research Center, Cleveland, Ohio 44135; telephone (216) 433-2320.

Dated: February 26, 1996.

Edward A. Frankle,  
*General Counsel.*

[FR Doc. 96-4988 Filed 3-4-96; 8:45 am]

BILLING CODE 7510-01-M

**[Notice 96-018]****Notice of Prospective Patent License**

**AGENCY:** National Aeronautics and Space Administration.

**ACTION:** Notice of Prospective Patent License.

**SUMMARY:** NASA hereby gives notice that Atlas Technology Corporation, of 6000 Park of Commerce, Boulevard, Suite E, Boca Raton, Florida 33487, has requested an exclusive license to practice the invention protected by U.S. Patent No. 5,355,724 entitled "Optical Broadcasting Wind Indicator," which was issued on October 18, 1994, and is assigned to the National Aeronautics and Space Administration. Written objections to the prospective grant of a license should be sent to Mr. William J. Sheehan, Patent Counsel, Kennedy Space Center.

**DATES:** Response to this notice must be received by (insert 60 days from date of publication in the Federal Register).

**FOR FURTHER INFORMATION CONTACT:** Mr. William J. Sheehan, Patent Attorney, Kennedy Space Center, Mail Code DE-TPO, Kennedy Space Center, FL 32899; (407) 867-2544.

Dated: February 26, 1996.

Edward A. Frankle,  
*General Counsel.*

[FR Doc. 96-4991 Filed 3-4-96; 8:45 am]

BILLING CODE 7510-01-M

**[Notice 96-022]****Notice of Prospective Patent License**

**AGENCY:** National Aeronautics and Space Administration.

**ACTION:** Notice of Prospective Patent License.

**SUMMARY:** NASA hereby gives notice that The Invention Factory, P.O. Box 1033, Waitsfield, Vermont 05673, has applied for a partially exclusive license to practice the invention described and claimed in U.S. Patent No. 5,373,100, entitled "Ion Exchange Polymer and Method of Making," which is assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. The field of use will be limited to removal of heavy metals from aqueous foods, including maple syrup, other than water. Written objections to the prospective grant of a license to The Invention Factory should be sent to Mr. Kent Stone.

**DATES:** Responses to this Notice must be received by (insert 60 days from date of publication in the Federal Register).

**FOR FURTHER INFORMATION CONTACT:** Mr. Kent Stone, Patent Attorney, NASA Lewis Research Center, Cleveland, Ohio 44135; telephone (216) 433-2320.

Dated: February 26, 1996.

Edward A. Frankle,  
*General Counsel*

[FR Doc. 96-4987 Filed 3-4-96; 8:45 am]

BILLING CODE 7510-01-M

**[Notice 96-024]****Notice of Prospective Patent License**

**AGENCY:** National Aeronautics and Space Administration.

**ACTION:** Notice of Prospective Patent License.

**SUMMARY:** NASA hereby gives notice that Lee Associates, Inc. of 313 West Shore Road, South Hero, Vermont 05486, has applied for a partially exclusive license to practice the invention described and claimed in U.S. Patent No. 5,373,110, entitled "Ion Exchange Polymer and Method of Making," which is assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration.

The fields of use will be limited to: (i) Test kits for water purity; and (ii) recovery of precious metals for ores and electroplating processing materials. Written objections to the prospective grant of a license to Lee Associates, Inc. should be sent to Mr. Kent Stone.

**DATES:** Responses to this Notice must be received by (insert 60 days from date of publication in the Federal Register).

**FOR FURTHER INFORMATION CONTACT:** Mr. Kent Stone, Patent Attorney, NASA Lewis Research Center, Cleveland, Ohio 44135; telephone (216) 433-2320.

Dated: February 26, 1996.

Edward A. Frankle,  
*General Counsel.*

[FR Doc. 96-5112 Filed 3-4-96; 8:45 am]

BILLING CODE 7510-01-M

**[Notice 96-017]****Notice of Prospective Patent License**

**AGENCY:** National Aeronautics and Space Administration.

**ACTION:** Notice of Prospective Patent License.

**SUMMARY:** NASA hereby gives notice that Microcosm, Inc., of Annapolis Junction, Maryland, has applied for an exclusive license to practice the invention described and claimed in U.S. Patent No. 5,485,482, entitled "Method for Design and Construction of Efficient, Fundamental Transverse Mode Selected, Diode Pumped, Solid State Lasers," which is assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. Written objections to the prospective grant of a license to Microcosm, Inc. should be sent to Mr. R. Dennis Marchant, Patent Counsel, NASA Goddard Space Flight Center, Code 204, Greenbelt, Maryland 20771.

**DATES:** Response to this Notice must be received by (insert 60 days from date of publication in the Federal Register).

**FOR FURTHER INFORMATION CONTACT:** Mr. R. Dennis Marchant, Patent Counsel, (301) 286-7351.

Dated: February 26, 1996.

Edward A. Frankle,  
*General Counsel.*

[FR Doc. 96-4992 Filed 3-4-96; 8:45 am]

BILLING CODE 7510-01-M

**[Notice 96-020]****Notice of Prospective Patent License**

**AGENCY:** National Aeronautics and Space Administration.

**ACTION:** Notice of Prospective Patent License.

**SUMMARY:** NASA hereby gives notice that Moen Incorporated of 15300 Al Moen Drive, North Olmstead, Ohio 44070, has applied for a partially exclusive license to practice the invention described and claimed in U.S. Patent No. 5,373,110, entitled "Ion Exchange Polymer and Method of Making," which is assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. The field of use will be limited to removal of lead from drinking water. Written objections to the prospective grant of a license to Moen Incorporated should be sent to Mr. Kent Stone.

**DATES:** Responses to this Notice must be received by (insert 60 days from date of publication in the Federal Register).

**FOR FURTHER INFORMATION CONTACT:** Mr. Kent Stone, Patent Attorney, NASA Lewis Research Center, Cleveland, Ohio 44135; telephone (216) 433-2320.

Dated: February 26, 1996.

Edward A. Frankle,

*General Counsel.*

[FR Doc. 96-4989 Filed 3-4-96; 8:45 am]

BILLING CODE 7510-01-M

## NATIONAL CREDIT UNION ADMINISTRATION

### Privacy Act of 1974; Amendment to an Existing System of Records

**AGENCY:** National Credit Union Administration.

**ACTION:** Amendment to an existing system of records.

**SUMMARY:** In accordance with the Privacy Act of 1974 (Privacy Act), the National Credit Union Administration (NCUA or NCUA Board) is publishing amendments to the existing system of records entitled Investigative Reports Involving Any Crime or Suspected Crime against a Credit Union, NCUA (NCUA 15) and is amending appendix B to its System of Records. The changes to NCUA 15 reflect a new interagency suspicious activity reporting process, combining the criminal referral and suspicious financial transactions reporting requirements of the federal financial regulatory agencies and the U.S. Department of the Treasury (Treasury), and involving the use of a new computerized database maintained by the Financial Crimes Enforcement Network (FinCEN), of the Treasury, on behalf of these agencies and Treasury. Additional changes are made to NCUA

15 to update the system. The changes to appendix B (which applies to all of NCUA Systems of Records) updates the listing of NCUA regional offices and the states covered by each region.

**EFFECTIVE DATE:** The revised system will become effective without further notice on April 1, 1996, unless comments postmarked, received or posted on NCUA's Electronic Bulletin Board on or before April 1 cause a contrary decision. If based on NCUA's review of comments received, changes are made, NCUA will publish a new notice.

**FOR FURTHER INFORMATION CONTACT:** Hattie M. Ulan, Special Counsel to the General Counsel, NCUA, 1775 Duke Street, Alexandria, VA 22314-3428.

**SUPPLEMENTARY INFORMATION:** Section (e)(4) of the Privacy Act of 1974, 5 U.S.C. 552a(e)(4) (Privacy Act), requires each agency to publish a notice of the establishment of or revision to each system of records maintained by the agency. The NCUA Board is amending existing system NCUA 15 by changing its name from "Investigative Reports Involving Any Crime or Suspected Crime Against a Credit Union, NCUA" to "Investigative Reports Involving Any Crime, Suspected Crime or Suspicious Activity Against a Credit Union, NCUA." Other changes to the system are discussed below. Exemption rules promulgated pursuant to exemption (k)(2) of the Privacy Act, 5 U.S.C. 552a(k)(2), continue to apply for the amended system.

Certain of the changes to the system reflect an agreement between FinCEN and the NCUA Board, the Office of the Comptroller of the Currency (OCC), the Federal Deposit Insurance Corporation (FDIC), the Office of Thrift Supervision (OTS), and the Federal Reserve Board (FRB) (the federal financial regulatory agencies) to store Suspicious Activity Reports (SAR) in electronic form in a database maintained by FinCEN and located in Detroit, Michigan. The SAR is being adopted by all federal financial regulatory agencies and by the Treasury as a replacement for the Criminal Referral Form, which has been in use by financial institutions to report suspected criminal activity by individuals to the federal financial regulatory agencies and the federal law enforcement authorities (see FRB, OCC and OTS proposed rulemakings at 60 FR 34481, July 3, 1995; 60 FR 34476, July 3, 1995; and 60 FR 36366, July 17, 1995; respectively). NCUA will be amending its criminal referral form regulation (12 CFR part 748) at a later date. Information from the Criminal Referral Form has always been included in the existing system and similar information will continue to be

collected by the SAR. In addition to reports of suspected criminal activity, the SAR will also allow a credit union or other financial institution to report suspicious financial transactions under federal money laundering statutes, pursuant to Treasury regulations, (31 CFR part 103). Some of this information is currently reported on currency transaction reports required to be filed by financial institutions. Only the information collected by the SAR, and its status updates, will be located in the database maintained by FinCEN; all other information in the system will be located at the NCUA.

Pursuant to the interagency agreement between FinCEN and the federal financial regulatory agencies, FinCEN will manage a computerized database containing the SAR and status updates, which is information currently collected and/or maintained separately by each of the federal financial regulatory agencies. With regard to this database, only those records that are generated under the jurisdiction of the NCUA Board are considered to be NCUA records for purposes of the Privacy Act. Access to and use of these NCUA records by other agencies will continue to be governed by the routine uses in NCUA's System 15.

Accordingly, the "Routine Uses" element is being amended to reflect the sharing among federal financial regulatory agencies and law enforcement agencies of the information collected by the SAR and the status updates. Additionally, the "Safeguards" element is amended to add that on-line access to the computerized database maintained by FinCEN is limited to authorized individuals who have been specified by each federal financial regulatory agency and Treasury, and who have been issued a nontransferable identifier or password.

Other amendments reflect an overall update to the system including the addition of "persons participating in the affairs of a credit union" as a category of individuals covered by the system; the addition of a paragraph explaining the purpose of the system; the addition of several routine uses and record source categories; and changes in the system manager and address. The exemption for this system of records continues to be (k)(2), because the information consists of investigatory material compiled for law enforcement purposes.

The NCUA Board is also updating appendix B to its Systems of Records, to reflect correct addresses for the six NCUA regional offices and the states covered by each.



In accordance with 5 U.S.C. 552(r), a report of this amended system of records is being filed with the President of the Senate, the Speaker of the House of Representatives, and the Director of the Office of Management and Budget (OMB). OMB has oversight authority over agency implementation of the Privacy Act. This amended system of records will become effective on April 1, 1996, without further notice, unless the Board publishes a notice to the contrary in the Federal Register.

Accordingly, the Board has amended the system of records NCUA 15, newly entitled "Investigative Reports Involving Any Crimes, Suspected Crime or Suspicious Activity Against a Credit Union, NCUA", and appendix B to its Systems of Records as follows:

#### **NCUA-15**

##### **SYSTEM NAME:**

Investigative Reports Involving Any Crime, Suspected Crime or Suspicious Activity Against a Credit Union, NCUA.

##### **SYSTEM LOCATION:**

Office of General Counsel, National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314-3428. Computerized records of Suspicious Activity Reports (SAR), with status updates, are managed by the Financial Crimes Enforcement Network (FinCEN), Department of the Treasury, pursuant to a contractual agreement, and are stored in Detroit, Michigan. Authorized personnel at NCUA's Central Office and six regional offices have on-line access to the computerized database managed by FinCEN through individual work stations that are linked to the database central computer.

##### **CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Directors, officers, committee members, employees, agents, and persons participating in the conduct of the affairs of federally insured credit unions who are reported to be involved in suspected criminal activity or suspicious financial transactions and are referred to law enforcement officials; and other individuals who have been involved in irregularities, violations of law, or unsafe or unsound practices referenced in documents received by the NCUA in the course of exercising its supervisory functions.

##### **CATEGORIES OF RECORDS IN THE SYSTEM:**

Inter- and intra-agency correspondence, memoranda and reports. The SAR contains information identifying the credit union involved, the suspected person, the type of

suspicious activity involved, and any witnesses.

##### **AUTHORITY FOR MAINTENANCE OF THE SYSTEM:** 12 U.S.C. 1786 and 1789.

##### **PURPOSE(S):**

The overall system serves as a NCUA repository for investigatory or enforcement information related to its responsibility to examine and supervise federally insured credit unions. The system maintained by FinCEN serves as the database for the cooperative storage, retrieval, analysis, and use of information relating to Suspicious Activity Reports made to or by the NCUA Board, the Federal Reserve Board, the Office of the Comptroller of the Currency, the Federal Deposit Insurance Corporation, the Office of Thrift Supervision, (collectively, the federal financial regulatory agencies), and FinCEN to various law enforcement agencies for possible criminal, civil, or administrative proceedings based on known or suspected violations affecting or involving persons, financial institutions, or other entities under the supervision or jurisdiction of such federal financial regulatory agencies.

##### **ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS, AND THE PURPOSES OF SUCH USES:**

Information in these records may be used to:

- (1) Determine if any further agency action should be taken.
- (2) Provide the federal financial regulatory agencies and FinCEN with information relevant to their operations;
- (3) Disclose information to third parties during the course of an investigation to the extent necessary to obtain information pertinent to the investigation;
- (4) With regard to formal or informal enforcement actions; release information pursuant to 12 U.S.C. 1786(s), which requires the NCUA Board to publish and make available to the public final orders and written agreements, and modifications thereto; and
- (5) Standard routine uses as set forth in appendix A.

##### **POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

##### **STORAGE:**

The records will be maintained in electronic data processing systems and paper files.

##### **RETRIEVABILITY:**

Computer output and file folders are retrievable by indexes of data fields, including name of the credit union, NCUA Region, and individuals' names.

##### **SAFEGUARDS:**

Paper records and word processing discs are stored at the NCUA in lockable metal file cabinets. The database maintained by FinCEN complies with applicable security requirements of the Department of the Treasury. On-line access to the information in the database is limited to authorized individuals who have been designated by each federal financial regulatory agency and FinCEN, and each such individual has been issued a nontransferable identifier or password.

##### **RETENTION AND DISPOSAL:**

Records are maintained indefinitely.

##### **SYSTEM MANAGER(S) AND ADDRESS:**

General Counsel, NCUA, 1775 Duke Street, Alexandria, VA 22314-3428.

##### **NOTIFICATION PROCEDURES:**

Inquiries should be sent to the System Manager as noted above.

##### **RECORD ACCESS PROCEDURES:**

Same as "Notification procedure" above.

##### **CONTESTING RECORDS PROCEDURES:**

Same as "Notification procedure" above.

##### **RECORD SOURCE CATEGORIES:**

Information received by the NCUA Board from various sources, including, but not limited to law enforcement and other agency personnel involved in sending inquiries to the NCUA Board, NCUA examiners, credit union officials, employees, and members. The information maintained by FinCEN is compiled from SAR and related historical and updating forms compiled by financial institutions, the NCUA Board, and the other federal financial regulatory agencies for law enforcement purposes.

##### **SYSTEM EXEMPTED FROM CERTAIN PROVISIONS OF THE PRIVACY ACT:**

This system is exempt from 5 U.S.C. 552a(c)(3), (d)(1), (d)(2), (d)(3), (d)(4), (e)(1), (e)(4) (G), (H) and (I), and (f) of the Privacy Act pursuant to 5 U.S.C. 552a(k)(2).

##### **Appendix B—List of Regional Offices (Addresses and States Covered by Each Region)**

I. NCUA Region I Office: 9 Washington Square, Washington Avenue Extension, Albany, NY 12205, Phone: 518-464-4180, FAX: 518-464-4195. States covered: Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, Vermont.

II. NCUA Region II Office: 1775 Duke Street, Suite 4206, Alexandria, VA 22314-3437, Phone: 703-838-0401, FAX: 703-838-0571. States covered: Delaware, District of



Columbia, Maryland, New Jersey, Pennsylvania, Virginia, West Virginia.

III. NCUA Region III Office: 7000 Central Parkway, Suite 1600, Atlanta, GA 30328, Phone: 404-396-4042, FAX: 404-698-8211. States covered: Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, Puerto Rico, South Carolina, Tennessee, Virgin Islands.

IV. NCUA Region IV Office: 4225 Naperville Road, Suite 125, Lisle, IL 60532, Phone: 708-245-1000, FAX: 708-245-1016. States covered: Illinois, Indiana, Michigan, Missouri, Ohio, Wisconsin.

V. NCUA Region V Office: 4807 Spicewood Springs Road, Suite 5200, Austin, TX 78759-8490, Phone 512-482-4500, FAX: 512-482-4511. States covered: Arizona, Colorado, Iowa, Kansas, Minnesota, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, Utah, Wyoming.

VI. NCUA Region VI Office: 2300 Clayton Road, Suite 1350, Concord, CA 94520, Phone: 510-825-6125, FAX: 510-486-3729. States covered: Alaska, American Samoa, California, Guam, Hawaii, Idaho, Montana, Nevada, Oregon, Washington.

By the National Credit Union Administration Board on this 29th day of February, 1996.

Becky Baker,

*Secretary of the Board.*

[FR Doc. 96-5111 Filed 3-4-96; 8:45 am]

BILLING CODE 7535-01-U

## NUCLEAR REGULATORY COMMISSION

### Sunshine Act Meeting

#### NUCLEAR REGULATORY COMMISSION

**DATE:** Weeks of March 4, 11, 18, and 25, 1996.

**PLACE:** Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

**STATUS:** Public and Closed.

#### MATTERS TO BE CONSIDERED:

Week of March 4

*Thursday, March 7*

4:00 p.m.

Affirmation Session (Public Meeting)  
a. Cleveland Electric Illuminating Co.—  
Licensee's Petition for Review of LBP-  
95-17

(Contact: Andrew Bates, 301-415-1963)

*Friday, March 8*

1:00 p.m.

Briefing by Low Level Waste Forum  
(LLWF) (Public Meeting)  
(Contact: Jim Kennedy, 301-415-6668)

2:30 p.m.

Briefing on Design Certification Issues  
(Public Meeting)  
(Contact: Ted Quay, 301-415-1118)

Week of March 11—Tentative

There are no meetings scheduled for the Week of March 11.

Week of March 18—Tentative

*Tuesday, March 19*

10:30 a.m.

Briefing on U.S. Enrichment Corporation  
Certification (Public Meeting)  
(Contact: John Hickey, 301-415-7192)

Week of March 25—Tentative

*Wednesday, March 27*

10:30 a.m.

Meeting with Nuclear Safety Research  
Review Committee (NSRRC) (Public  
Meeting)  
(Contact: Jose Cortez, 301-415-6596)

**ADDITIONAL INFORMATION:** By a vote of 3-0 on February 27, the Commission determined pursuant to U.S.C. 552b(e) and § 9.107(a) of the Commission's rules that "Affirmation of 'Sequoyah Fuel Corporation and General Atomics; LBP-95-18 Approving Joint Settlement with Sequoyah Fuels Corp.' and 'Yankee Atomic Electric Company (Yankee Nuclear Power Station), Docket No. 50-029'" (PUBLIC MEETING) be held on February 27, and on less than one week's notice to the public.

The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (Recording)—(301) 415-1292.

**CONTACT PERSON FOR MORE INFORMATION:**  
Bill Hill (301) 415-1661.

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to it, please contact the Office of the Secretary, Attn: Operations Branch, Washington, D.C. 20555 (301-415-1963).

In addition, distribution of this meeting notice over the internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to alb@nrc.gov or gkt@nrc.gov.

Dated: February 29, 1996.

William M. Hill, Jr.,

*SECY Tracking Officer, Office of the Secretary.*

[FR Doc. 96-5208 Filed 3-1-96; 11:41 am]

BILLING CODE 7590-01-M

## OFFICE OF MANAGEMENT AND BUDGET

### Budget Rescissions and Deferrals

The White House,  
*Washington, February 21, 1996.*

Dear Mr. Speaker: In accordance with the Congressional Budget and Impoundment Control Act of 1974, I herewith report three rescission proposals of budgetary resources, totaling \$820 million. These rescissions offset the emergency FY 1996 Defense supplemental appropriations, which support the Bosnia peace implementation force. The rescissions affect the Department of Defense.

Sincerely,  
William J. Clinton

The Honorable Newt Gingrich,  
Speaker of the House of Representatives,  
Washington, D.C. 20515.

Note: A secret attachment to this document was not included in the original received by the Office of the Federal Register and is not published in the Federal Register.

#### Department of Defense

### *Research, Development, Test & Evaluation, Air Force*

*Of the amounts appropriated in fiscal year 1995 "Research, Development, Test & Evaluation, Air Force," \$245,000,000 is hereby rescinded.*

These funds are excess to requirements and are recommended for rescission to fund higher priority costs associated with the Bosnia peace implementation force.

#### Department of Defense

### *Research, Development, Test & Evaluation, Air Force*

*Of the amounts appropriated in fiscal year 1995 "Other Procurement, Air Force," \$265,000,000 is hereby rescinded.*

These funds are excess to requirements and are recommended for rescission to fund higher priority costs associated with the Bosnia peace implementation force.

#### Department of Defense

### *Research, Development, Test & Evaluation, Air Force*

*Of the amounts appropriated in fiscal year 1995 "Missile Procurement, Air Force," \$310,000,000 is hereby rescinded.*

These funds are excess to requirements and are recommended for rescission to fund higher priority costs associated with the Bosnia peace implementation force.

[FR Doc. 96-5028 Filed 3-4-96; 8:45 am]

BILLING CODE 3110-01-P

## OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

### USTR Announces Allocation of the Tariff-rate Quota Increase for Raw Cane Sugar

**AGENCY:** Office of the United States Trade Representative.

**ACTION:** Notice.

**SUMMARY:** The Office of the United States Trade Representative (USTR) is providing notice of the country-by-country allocation of the 400,000 metric ton increase in the tariff-rate quota for imported raw cane sugar for the period

that begins October 1, 1995, and ends September 30, 1996. This is in addition to the previous allocations of the tariff-rate quota of 1,417,195 mt for imported raw cane sugar.

**EFFECTIVE DATE:** January 17, 1996.

**ADDRESSES:** Inquiries may be mailed or delivered to Tom Perkins, Senior Economist, Office of Agricultural Affairs (Room 421), Office of the United States Trade Representative, 600 17th Street, NW., Washington, DC 20508.

**FOR FURTHER INFORMATION CONTACT:**

Tom Perkins, Office of Agricultural Affairs, 202-395-6127.

**SUPPLEMENTARY INFORMATION:** Pursuant to Additional U.S. Note 5 to chapter 17 of the Harmonized Tariff Schedule of the United States (HTS), the United States maintains a tariff-rate quota for imports of raw sugar. the in-quota quantity of the tariff-rate quota for the period October 1, 1995-September 30, 1996, has been increased by 400,000 metric tons by the Secretary of Agriculture, resulting in a new total of 1,817,195 metric tons, raw value.

Section 404(d)(3) of the Uruguay Round Agreements Act (19 U.S.C. 3601(d)(3)) authorizes the President to allocate the in-quota quantity of a tariff-rate quota for any agricultural product

among supplying countries or customs areas. The President delegated this authority to the United States Trade Representative under paragraph (3) of Presidential Proclamation No. 6763 (60 FR 1007).

I have determined to allocate the increase in the tariff-rate quota among supplying countries or customs areas. Accordingly, the country-by-country tariff-rate quota allocations in metric tons, raw value, for raw cane sugar allowed into the United States at the in-quota quantity tariff rate for the October 1, 1995-September 30, 1996, period are as follows:

**1995-96 RAW SUGAR TRQ ALLOCATION**

[In Metric tons]

Country	Current fiscal year 1996 allocation	Additional allocation	New fiscal year 1996 allocation
Argentina .....	58,285	17,339	75,623
Australia .....	112,503	33,468	145,971
Barbados .....	9,488	2,823	12,311
Belize .....	14,910	4,435	19,346
Bolivia .....	10,844	3,226	14,069
Brazil .....	196,541	58,468	255,009
Colombia .....	32,531	9,677	42,208
Congo .....	7,258	0	7,258
Conte d'Ivoire .....	7,258	0	7,258
Costa Rica .....	20,332	6,048	26,380
Dominical Republic .....	238,561	70,968	309,528
Ecuador .....	14,910	4,435	19,346
El Salvador .....	35,242	10,484	45,726
Fiji .....	12,199	3,629	15,828
Gabon .....	7,258	0	7,258
Guatemala .....	65,062	19,355	84,417
Guyana .....	16,265	4,839	21,104
Haiti .....	7,258	0	7,258
Honduras .....	13,555	4,032	17,587
India .....	10,844	3,226	14,069
Jamaica .....	14,910	4,435	19,346
Madagascar .....	7,258	0	7,258
Malawi .....	13,555	4,032	17,587
Mauritius .....	16,265	4,839	21,104
Mexico .....	7,258	0	7,258
Mozambique .....	17,621	5,242	22,863
Nicaragua .....	28,465	8,468	36,932
Panama .....	39,308	11,694	51,002
Papua New Guinea .....	7,258	0	7,258
Paraguay .....	7,258	0	7,258
Peru .....	55,574	16,532	72,106
Philippines .....	182,987	54,435	237,422
South Africa .....	31,176	9,274	40,450
St. Kitts & Nevis .....	7,258	0	7,258
Swaziland .....	21,687	6,452	28,139
Taiwan .....	16,265	4,839	21,104
Thailand .....	18,976	5,645	24,622
Trinidad-Tobago .....	9,488	2,823	12,311
Uruguay .....	7,258	0	7,258
Zimbabwe .....	16,265	4,839	21,104
<b>Total .....</b>	<b>1,417,195</b>	<b>400,000</b>	<b>1,817,195</b>

The allocation includes the following minimum quota-holding countries: Congo Cote d'Ivoire, Gabon, Haiti, Madagascar, Mexico, Papua New Guinea, Paraguay, St. Kitts & Nevis, and Uruguay.

Michael Kantor,

*United States Trade Representative.*

[FR Doc. 96-4777 Filed 3-4-96; 8:45 am]

BILLING CODE 3190-01-M

## SECURITIES AND EXCHANGE COMMISSION

[Rel. No. IC-21789; File No. 812-9746]

### Tomorrow Funds Retirement Trust, et al.

February 27, 1996.

**AGENCY:** Securities and Exchange Commission ("SEC" or "Commission").

**ACTION:** Notice of Application for Exemption under the Investment Company Act of 1940 (the "1940 Act").

**APPLICANTS:** Tomorrow Funds Retirement Trust (the "Trust"), and Weiss, Peck & Greer, L.L.C. (the "Adviser").

**RELEVANT 1940 ACT SECTIONS:** Order requested under Section 6(c) of the 1940 Act for exemptions from the provisions of Sections 9(a), 13(a), 15(a) and 15(b) of the 1940 Act and Rules 6e-2(b)(15) and 6e-3(T)(b)(15) thereunder.

**SUMMARY OF APPLICATION:** Applicants seek an order to the extent necessary to permit shares of the Trust and beneficial interests and/or shares of any other investment company (or series thereof) that is designed to fund variable insurance products and for which the Adviser, or any of its affiliates, may serve now or in the future, as investment adviser, administrator, manager, principal underwriter or sponsor (collectively, "Insurance Products Funds") to be sold to and held by (a) variable annuity and variable life separate accounts of both affiliated and unaffiliated life insurance companies ("Participating Insurance Companies"), and (b) qualified pension and retirement plans ("Qualified Plans").

**FILING DATE:** The application was filed on September 6, 1995, and amended on February 20, 1996.

**HEARING AND NOTIFICATION OF HEARING:** An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Secretary of the Commission and serving Applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC

by 5:30 p.m. on March 25, 1996, and should be accompanied by proof of service on Applicants in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the requester's interest, the reason for the request and the issues contested. Persons may request notification of a hearing by writing to the Secretary of the Commission.

**ADDRESSES:** Secretary, SEC, 450 Fifth Street, N.W., Washington, D.C. 20549. Applicants, Jay C. Nadel, Weiss, Peck & Greer, L.L.C., One New York Plaza, New York, New York 10004.

**FOR FURTHER INFORMATION CONTACT:** Mark C. Amorosi, Attorney, or Patrice M. Pitts, Special Counsel, Office of Insurance Products, Division of Investment Management, at (202) 942-0670.

**SUPPLEMENTARY INFORMATION:** Following is a summary of the application. The complete application is available for a fee from the Public Reference Branch of the Commission.

#### Applicants' Representations

1. The Trust is a series Delaware business trust which is registered under the 1940 Act as an open-end management investment company. The Trust consists of six diversified series mutual funds (collectively, the "Funds"). The Trust's initial registration statement on Form N-1A was declared effective on November 21, 1995.<sup>1</sup>

2. Each Fund of the Trust is authorized to offer two classes of shares. The Adviser Class of shares may be purchased only by Qualified Plans. The Institutional Class of shares may be purchased by Qualified Plans or by separate accounts of Participating Insurance Companies to serve as investment vehicles for variable annuity and variable life insurance contracts.

3. Various fees and charges are imposed by the Trust. The Tomorrow Post-Retirement Fund will pay the Adviser a monthly fee equal on an annual basis to 0.65% of its average daily net assets. The remaining Funds will each pay the Adviser a monthly fee equal on an annual basis to 0.75% of the Fund's average daily net assets. Pursuant to an administration agreement, the Adviser also will serve as administrator for each Fund for which the Adviser will receive a fee, computed daily and payable monthly, at an annual rate equal to 0.09% of each Fund's average daily net assets.

4. Applicants state that the Trust, on behalf of each Fund, has adopted a service plan pursuant to which each

Fund pays service fees at an aggregate annual rate of up to 0.25% of a Fund's average daily net assets attributable to the Institutional Class shares. The service fee is intended to be compensation for Qualified Plan fiduciaries for providing personal services and/or account maintenance services to the underlying beneficial owners of the Institutional Class shares. The Trust, on behalf of the applicable Fund, will make monthly payments to Qualified Plan fiduciaries based on the average net asset value of the Institutional Class shares which are attributable to the applicable Qualified Plan.

5. Shares of the Insurance Products Funds will be offered to separate accounts of other insurance companies, including insurance companies that are not affiliated with one another, to serve as the investment vehicle for various types of insurance products, which may include variable annuity contracts, single premium variable life insurance contracts, scheduled premium variable life insurance contracts and flexible premium variable life insurance contracts.

6. Applicants state that upon commencement of operation, each Fund of the Trust will be managed and its shares will be distributed by the Adviser which will not be affiliated with any Participating Insurance Company whose variable contracts utilize the Trust as the underlying investment. The Adviser, a Delaware limited liability company, consists of 44 general principals, one of whom is a member of the New York Stock Exchange, and certain associate principals. The Adviser, together with its wholly-owned subsidiary, Weiss, Peck & Greer Advisers, Inc., acts as investment adviser for approximately \$13 billion of institutional and private investment accounts.

#### Applicants' Legal Analysis

1. In connection with the funding of scheduled premium variable life insurance contracts issued through a separate account registered under the 1940 Act as a unit investment trust, Rule 6e-2(b)(15) provides partial exemptions from Sections 9(a), 13(a), 15(a) and 15(b) of the 1940 Act.<sup>2</sup> The exemptions granted by Rule 6e-2(b)(15) are available only where a management investment company underlying a unit investment trust ("underlying fund") offers its shares "exclusively to variable life insurance separate accounts of the life insurer, or of any affiliated life

<sup>2</sup> The relief provided by Rule 6e-2 is available to a separate account's investment adviser, principal underwriter, and sponsor or depositor.

<sup>1</sup> File Nos. 33-60841 and 811-7315.

insurance company." Therefore, the relief granted by Rule 6e-2(b)(15) is not available with respect to a scheduled premium variable life insurance separate account that owns shares of an underlying fund that also offers its shares to a variable annuity separate account of the same company or of any affiliated or unaffiliated life insurance company. The use of a common management investment company as the underlying investment medium for both variable annuity and variable life insurance separate accounts of a single insurance company or of any affiliated insurance company is referred to herein as "mixed funding."

2. In addition, the relief granted by Rule 6e-2(b)(15) is not available with respect to a scheduled premium variable life insurance separate account that owns shares of an underlying fund that also offers its shares to separate accounts funding variable contracts of one or more unaffiliated life insurance companies. The use of a common management investment company as the underlying investment medium for variable life insurance separate accounts of one insurance company and separate accounts funding variable contracts of one or more unaffiliated life insurance companies is referred to herein as "shared funding."

3. In connection with the funding of flexible premium variable life insurance contracts issued through a unit investment trust, Rule 6e-3(T)(b)(15) provides partial exemptions from Sections 9(a), 13(a), 15(a), and 15(b) of the 1940 Act.<sup>3</sup> The exemptions granted by Rule 6e-3(T) are available only where a unit investment trust's underlying fund offers its shares "exclusively to separate accounts of the life insurer, or of any affiliated life insurance company, offering either scheduled contracts or flexible contracts, or both; or which also offer their shares to variable annuity separate accounts of the life insurer or of an affiliated life insurance company \* \* \*." Therefore, Rule 6e-3(T) permits mixed funding for flexible premium variable life insurance. However, Rule 6e-3(T) does not permit shared funding because the relief granted by Rule 6e-3(T)(b)(15) is not available with respect to a flexible premium variable life insurance separate account that owns shares of an underlying fund that also offers its shares to separate accounts (including flexible premium variable

life insurance separate accounts) of unaffiliated life insurance companies.

4. Applicants state that the relief granted by Rules 6e-2(b)(15) and 6e-3(T)(b)(15) is not affected by the purchase of shares of an Insurance Products Fund by a Qualified Plan. Applicants note, however, that exemptive relief is requested with respect to the sale of shares to Qualified Plans because the separate accounts investing in the Insurance Products Funds are themselves investment companies seeking relief under Rules 6e-2 and 6e-3(T) and do not wish to be denied such relief if the Insurance Products Funds sell shares to Qualified Plans.

5. Applicants state that in 1989, due to changes in the tax law, underlying funds such as the Trust were afforded the opportunity to increase their asset base through the sale of shares of the Insurance Products Funds to Qualified Plans. Applicants state that Section 817(h) of the Internal Revenue Code of 1986, as amended (the "Code"), imposes certain diversification standards on the underlying assets of variable contracts. The Code provides that such contracts shall not be treated as annuity contracts or life insurance contracts for any period in which the investments are not, in accordance with regulations prescribed by the Department of the Treasury, adequately diversified. On March 2, 1989, the Department of the Treasury issued regulations which established diversification requirements for the investment portfolios underlying variable contracts. Treas. Reg. § 1.817-5 (1989). The regulations provide that, to meet the diversification requirements, all of the beneficial interests in the investment company must be held by the segregated asset accounts of one or more insurance companies. The regulations do, however, contain certain exceptions to this requirement, one of which allows shares in an investment company to be held by the trustee of a qualified pension or retirement plan without adversely affecting the ability of shares in the same investment company also to be held by the separate accounts of insurance companies in connection with their variable contracts. Treas. Reg. § 1.817-5(f)(3)(iii).

6. Applicants state that the promulgation of Rules 6e-2 and 6e-3(T) under the 1940 Act preceded the issuance of these Treasury regulations. Applicants assert that, given the then current tax law, the sale of shares of the same investment company to both separate accounts and qualified pension and retirement plans could not have been envisioned at the time of the

adoption of Rules 6e-2(b)(15) and 6e-3(T)(b)(15).

7. Applicants therefore request that the Commission, under its authority in Section 6(c) of the 1940 Act, grant relief from Sections 9(a), 13(a), 15(a) and 15(b) of the 1940 Act and Rules 6e-2(b)(15) and 6e-3(T)(b)(15) thereunder to the extent necessary to permit mixed and shared funding.

8. Section 9(a) of the 1940 Act provides that is unlawful for any company to serve as an investment adviser to, or principal underwriter for, any registered open-end investment company if an affiliated person of that company is subject to any disqualification specified in Sections 9(a)(1) or 9(a)(2). Rule 6e-2(b)(15) (i) and (ii) and Rule 6e-3(T)(b)(15) (i) and (ii) provide exemptions from Section 9(a) under certain circumstances, subject to limitations on mixed and shared funding. The relief provided by Rules 6e-2(b)(15)(i) and 6e-3(T)(b)(15)(i) permits a person disqualified under Section 9(a) to serve as an officer, director, or employee of the life insurer, or any of its affiliates, so long as that person does not participate directly in the management or administration of the underlying fund. The relief provided by Rules 6e-2(b)(15)(ii) and 6e-3(T)(b)(15)(ii) permits the life insurer to serve as the underlying fund's investment adviser or principal underwriter, provided that none of the insurer's personnel who are ineligible pursuant to Section 9(a) participate in the management or administration of the fund.

9. Applicants state that the partial relief granted in Rules 6e-2(b)(15) and 6e-3(T)(b)(15) from the requirements of Section 9(a), in effect, limits the monitoring of an insurer's personnel that would otherwise be necessary to ensure compliance with Section 9 to that which is appropriate in light of the policy and purposes of Section 9. Applicants state that Rules 6e-2 and 6e-3(T) recognize that it is not necessary for the protection of investors or for the purposes fairly intended by the policy and provisions of the 1940 Act to apply the provisions of Section 9(a) to the many individuals employed by the Participating Insurance Companies, most of whom will have no involvement in matters pertaining to an investment company within that organization. Applicants note that the Participating Insurance Companies are not expected to play any role in the management or administration of the Insurance Products Funds. Therefore, Applicants submit that there is no regulatory reason to apply the provisions of section 9(a) to the many individuals in various

<sup>3</sup> The relief provided by Rule 6e-3(T) is available to a separate account's investment adviser, principal underwriter, and sponsor or depositor.

unaffiliated insurance companies (or affiliated companies of Participating Insurance Companies) that may utilize the Trust as the funding medium for variable contracts.

10. Rules 6e-2(b)(15)(iii) and 6e-3(T)(b)(15)(iii) provide partial exemptions from Sections 13(a), 15(a), and 15(b) of the 1940 Act to the extent that those sections have been deemed by the Commission to require "pass-through" voting with respect to management investment company shares held by a separate account, to permit the insurance company to disregard the voting instructions of its contract owners in certain limited circumstances.

11. Rules 6e-2(b)(15)(iii)(A) and 6e-3(T)(b)(15)(iii)(A) provide that an insurance company may disregard voting instructions of its contract owners with respect to the investment of an underlying investment company or any contract between an investment company and its investment adviser when required to do so by an insurance regulatory authority.

12. Rules 6e-2(b)(15)(iii)(B) and 6e-3(T)(b)(15)(iii)(B) provide that an insurance company may disregard contract owners' voting instructions if the contract owners initiate any change in such company's investment policies or any principal underwriter or investment adviser, provided that disregarding such voting instructions is reasonable and subject to other provisions of paragraphs (b)(5)(ii) and (b)(7)(ii) (B) and (C) of each Rule.

13. Applicants state that Rule 6e-2 recognizes that variable life insurance contracts have important elements unique to insurance contracts and are subject to extensive state regulation. Applicants maintain, therefore, that, in adopting Rule 6e-2, the Commission expressly recognizes that exemptions from pass-through voting requirements were necessary "to assure the solvency of the life insurer and the performance of its contractual obligations by enabling an insurance regulatory authority or the life insurer to act when certain proposals reasonably could be expected to increase the risks undertaken by the life insurer." Applicants state that flexible premium variable life insurance contracts and variable annuity contracts are subject to substantially the same state insurance regulatory authority, and therefore, the corresponding provisions of Rule 6e-3(T) presumably were adopted in recognition of the same considerations as the Commission applied in adopting Rule 6e-2. Applicants argue that these considerations are no less important or necessary when an insurance company

funds its separate accounts on a mixed and shared funds basis and that such funding does not compromise the goals of the insurance regulatory authorities or of the Commission.

14. Applicants assert that the sale of shares to Qualified Plans will not have any impact on the relief requested in this regard. Shares of the Insurance Products Funds sold to Qualified Plans will be held by the trustees of the Qualified Plans as mandated by Section 403(a) of the Employee Retirement Income Security Act of 1974 ("ERISA"). Section 403(a) also provides that the trustee must have exclusive authority and discretion to manage and control the plan with two exceptions: (1) when the plan expressly provides that the trustee is subject to the direction of a named fiduciary who is not a trustee, in which case the trustees are subject to proper directions made in accordance with the terms of the plan and not contrary to ERISA, and (2) when the authority to manage, acquire, or dispose of assets of the plan is delegated to one or more investment managers pursuant to Section 402(c)(3) of ERISA. Unless one of the two exceptions stated in Section 403(a) applies, Qualified Plan trustees have the exclusive authority and responsibility for voting proxies. Where a named fiduciary appoints an investment manager, the investment manager has the responsibility to vote the shares held unless the right to vote such shares is reserved to the trustees or to the named fiduciary. In any event, there is no pass-through voting to the participants in Qualified Plans. Accordingly, Applicants note that, unlike the case with insurance company separate accounts, the issue of the resolution of material irreconcilable conflicts with respect to voting is not present with respect to Qualified Plans.

15. Applicants state that no increased conflicts of interest would be presented by the granting of the requested relief. Applicants assert that shared funding does not present any issues that do not already exist where a single insurance company is licensed to do business in several or all states. Applicants note that where Participating Insurance Companies are domiciled in different states, it is possible that the state insurance regulatory body in a state in which one Participating Insurance Company is domiciled could require action that is inconsistent with the requirements of insurance regulators in one or more other states in which other Participating Insurance Companies are domiciled. Applicants state that the possibility, however, is no different and no greater than exists where a single

insurer and its affiliates offer their insurance products in several states.

16. Applicants argue that affiliation does not reduce the potential, if any exists, for differences in state regulatory requirements. In any event, the conditions (adapted from the conditions included in Rule 6e-3(T)(15)) discussed below are designed to safeguard against any adverse effects that different state regulatory requirements may produce. If a particular state insurance regulator's decision conflicts with the majority of other state regulators, the affected insurer may be required to withdraw its separate account's investment in the relevant Insurance Products Funds.

17. Applicants also argue that affiliation does not eliminate the potential, if any exists, for divergent judgments as to when a Participating Insurance Company properly may disregard voting instructions of contract owners. Potential disagreement is limited by the requirement that the decision by the Participating Insurance Company to disregard voting instructions be both reasonable and based on specified good faith determinations. However, if a Participating Insurance Company's decision to disregard contract owner voting instructions represents a minority position or would preclude a majority vote approving a particular change, such Participating Insurance Company may be required, at the election of the relevant Insurance Products Funds, to withdraw its investment in that fund and no charge or penalty will be imposed as a result of such withdrawal.

18. Applicants state that there is no reason why the investment policies of an Insurance Products Fund with mixed funding would or should be materially different from what those policies would or should be if such investment company or series thereof funded only variable annuity or only variable life insurance contracts. Applicants therefore argue that there is no reason to believe that conflicts of interest would result from mixed funding. Moreover, Applicants state that, assuming it were possible, the Insurance Products Funds will not be managed to favor or disfavor any particular insurer or type of contract.

19. Applicants note that no single investment strategy can be identified as appropriate to a particular insurance product. Each pool of variable annuity and variable life insurance contract owners is composed of individuals of diverse financial status, age, insurance and investment goals. An investment company supporting even one type of

insurance product must accommodate those diverse factors.

20. A further note that Section 817 of the Code is the only section in the Code where separate accounts are discussed. Section 817(h) imposes certain diversification standards on the underlying assets of variable annuity contracts and variable life contracts held in the portfolios of management investment companies. Treasury Regulation 1.817-5(f)(3)(iii), which established diversification requirements for such portfolios, specifically permits, among other things, "qualified pension or retirement plans" and separate accounts to share the same underlying management investment company. Therefore, neither the Code, the Treasury regulations nor the Revenue Rulings thereunder recognize any inherent conflicts of interest if Qualified Plans, variable separate accounts and variable life insurance separate accounts all invest in the same management investment company.

21. While there are differences in the manner in which distributions are taxed for variable annuity contracts, variable life insurance contracts and Qualified Plans, Applicants state that the tax consequences do not raise any conflicts of interest. When distributions are to be made, and the separate account or the Qualified Plan is unable to net purchase payments to make the distributions, the separate account or the Qualified Plan will redeem shares of the affected Trust at their net asset value. The Qualified Plan will then make distributions in accordance with the terms of the Qualified Plan and the life insurance company will make distributions in accordance with the terms of the variable contract.

22. With respect to voting rights, Applicants state that it is possible to provide an equitable means of giving such voting rights to contract owners and to Qualified Plans. Applicants state that the transfer agent for each Insurance Products Fund will inform each Participating Insurance Company of its share ownership in each separate account, as well as inform the trustees of the Qualified Plans of their holdings. Each Participating Insurance Company will then solicit voting instructions in accordance with Rules 6e-2 and 6e-3(T).

23. Applicants argue that the ability of the Insurance Products Funds to sell their shares directly to Qualified Plans does not create a "senior security," as such term is defined under Section 18(g) of the 1940 Act, with respect to any contract owner as compared to a participant under a Qualified Plan. Regardless of the rights and benefits of

participants and contract owners under the respective Qualified Plans and contracts, the Qualified Plans and the separate accounts have rights only with respect to their respective shares of the Insurance Products Fund. Such shares may be redeemed only at net asset value. No shareholder of any Insurance Products Fund has any preference over any other shareholder with respect to distribution of assets or payment of dividends.

24. Finally, Applicants assert that there are no conflicts between variable contract owners of the separate accounts and participants under the Qualified Plans with respect to the state insurance commissioners' veto powers (direct with respect to variable life insurance and indirect with respect to variable annuities) over investment objectives. The basic premise of shareholder voting is that not all shareholders may agree that there are any inherent conflicts of interest between shareholders. The state insurance commissioners have been given the veto power in recognition of the fact that insurance companies cannot simply redeem their separate accounts out of one fund and invest in another fund. To accomplish such redemptions and transfers, complex, time-consuming transactions must be undertaken. On the other hand, trustees of Qualified Plans can make the decision quickly and implement the redemption of shares from an Insurance Products Fund and reinvest in another funding vehicle without the same regulatory impediments or, as is the case with most Qualified Plans, hold cash pending suitable investment. Based on the foregoing, Applicants maintain that even should there arise issues where the interests of contract owners and the interests of Qualified Plans conflict, the issues can be resolved almost immediately because trustees of the Qualified Plans can, independently, redeem shares out of the Insurance Products Fund.

25. Applicants state that various factors have kept certain insurance companies from offering variable annuity and variable life insurance contracts. These factors include the cost of organizing and operating an investment funding medium, the lack of expertise with respect to investment management and the lack of public name recognition of certain insurers as investment professionals. Applicants argue that use of the Insurance Products Funds as common investment media for variable contracts would ameliorate these concerns. Applicants submit that mixed and shared funding should benefit variable contract owners by: (a) eliminating a significant portion of the

costs of establishing and administering separate funds; (b) allowing for a greater amount of assets available for investment by the Insurance Products Funds, thereby promoting economies of scale, permitting greater safety through greater diversification, and/or making the addition of new portfolios more feasible; and (c) encouraging more insurance companies to offer variable contracts, resulting in increased competition with respect to both variable contract design and pricing, which can be expected to result in more product variation and lower charges.

#### Applicants' Conditions

The Applicants have consented to the following conditions:

1. A majority of the Board of Trustees or Directors (each, a "Board" and referred to herein collectively as "Boards") of each Insurance Products Fund will consist of persons who are not "interested persons" thereof, as defined by Section 2(a)(19) of the 1940 Act and the Rules thereunder and as modified by any applicable orders of the Commission, except that, if this condition is not met by reason of the death, disqualification, or bona fide resignation of any trustee or director, then the operation of this condition shall be suspended: (i) for a period of 45 days if the vacancy or vacancies may be filled by the Board; (ii) for a period of 60 days if a vote of shareholders is required to fill the vacancy or vacancies; or (iii) for such longer period as the Commission may prescribe by order upon application.

2. The Boards will monitor their respective Insurance Products Funds for the existence of any material irreconcilable conflict between the interests of the variable contract owners of all separate accounts investing in the Insurance Products Funds. A material irreconcilable conflict may arise for a variety of reasons, including: (a) state insurance regulatory authority action; (b) a change in applicable federal or state insurance, tax, or securities laws or regulations, or a public ruling, private letter ruling, or any similar action by insurance, tax, or securities regulatory authorities; (c) an administrative or judicial decision in any relevant proceeding; (d) the manner in which the investments of the Insurance Products Funds are being managed; (e) a difference in voting instructions given by variable annuity and variable life insurance contract owners; (f) a decision by a Participating Insurance Company to disregard contract owner voting instructions; and (g) if applicable, a decision by a Qualified Plan to

disregard the voting instructions of Qualified Plan participants.

3. Any Participating Insurance Company, the Adviser (or any other investment adviser of the Insurance Products Funds), and any Qualified Plan that executes a fund participation agreement upon becoming an owner of 10% or more of the assets of an Insurance Products Fund will report any potential or existing conflicts, of which they become aware, to the Board and will be obligated to assist the appropriate Board in carrying out its responsibilities under these conditions by providing the Board with all information reasonably necessary for the Board to consider any issues raised. This responsibility includes, but is not limited to, an obligation by each Participating Insurance Company and the Adviser to inform the Board whenever it has determined to disregard contract owner voting instructions and, if pass-through voting is applicable, an obligation by the Adviser and a Qualified Plan to inform the Board whenever it has determined to disregard Qualified Plan participant voting instructions. The responsibility to report such information and conflicts and to assist the Boards will be contractual obligations of the Adviser and all Participating Insurance Companies and Qualified Plans investing in Insurance Products Funds under their agreements governing participation therein, and such agreements shall provide that these responsibilities will be carried out with a view only to the interests of the contract owners, and if applicable, Qualified Plan participants.

4. If a majority of the Board of an Insurance Products Fund, or a majority of the disinterested members of such Board, determines that a material irreconcilable conflict exists, the Adviser and the relevant Participating Insurance Companies and Qualified Plans will, at their expense and to the extent reasonably practicable (as determined by a majority of disinterested trustees or directors), take whatever steps are necessary to remedy or eliminate the irreconcilable material conflict. Such steps could include: (a) withdrawing the assets allocable to some or all of the separate accounts from an Insurance Products Fund or any series thereof and reinvesting such assets in a different investment medium, which may include another series of the Insurance Products Fund or another Insurance Products Fund; (b) submitting the question of whether such segregation should be implemented to a vote of all affected variable contract owners and, as appropriate, segregating the assets of any appropriate groups

(i.e., variable annuity contract owners or variable life insurance contract owners of one or more Participating Insurance Companies) that votes in favor of such segregation, or offering to the affected variable contract owners the option of making such a change; and (c) establishing a new registered management investment company (or series thereof) or managed separate account. If a material irreconcilable conflict arises because of a Participating Insurance Company's decision to disregard contract owner voting instructions, and that decision represents a minority position or would preclude a majority vote, the Participating Insurance Company may be required, at the election of the relevant Insurance Products Fund, to withdraw its separate account's investment therein, and no charge or penalty will be imposed as a result of such withdrawal. If a material irreconcilable conflict arises because of a Qualified Plan's decision to disregard Qualified Plan participant voting instructions, if applicable, and that decision represents a minority position or would preclude a majority vote, the Qualified Plan may be required, at the election of the Insurance Products Fund to withdraw its investment in such Insurance Products Fund, and no charge or penalty will be imposed as a result of such withdrawal. The responsibility to take remedial action in the event of a Board determination of an irreconcilable material conflict and to bear the cost of such remedial action shall be a contractual obligation of the Adviser and all Participating Insurance Companies and Qualified Plans under their agreements governing participation in the Insurance Products Funds and these responsibilities will be carried out with a view only to the interests of the contract owners, and, if appropriate, Qualified Plan participants.

5. For purposes of condition 4, a majority of disinterested members of the applicable Board will determine whether any proposed action adequately remedies any irreconcilable material conflict, but in no event will the relevant Insurance Products Fund or the Adviser (or any other investment adviser of the Insurance Products Fund) be required to establish a new funding medium for any variable contract. No Participating Insurance Company shall be required by condition 4 to establish a new funding medium for any variable contract if an offer to do so has been declined by a vote of a majority of contract owners materially and adversely affected by the irreconcilable material conflict.

6. The determination by any Board of the existence of an irreconcilable material conflict and its implications shall be made known promptly in writing to the Adviser, all Participating Insurance Companies and Qualified Plans.

7. Participating Insurance Companies will provide pass-through voting privileges to all variable contract owners so long as the Commission continues to interpret the 1940 Act to require pass-through voting privileges for variable contract owners. Accordingly, the Participating Insurance Companies will vote shares of an Insurance Products Fund held in their separate accounts in a manner consistent with voting instructions timely received from variable contract owners. Participating Insurance Companies will be responsible for assuring that each of their separate accounts that participates in the Insurance Products Funds calculates voting privileges in a manner consistent with other Participating Insurance Companies. The obligation to calculate voting privileges in a manner consistent with all other separate accounts investing in the Insurance Products Fund will be a contractual obligation of all Participating Insurance Companies under the agreements governing their participation in the Insurance Products Fund. Each Participating Insurance Company will vote shares for which it has not received timely voting instructions as well as shares attributable to it in the same proportion as it votes those shares for which it has received voting instructions. Each Qualified Plan will vote as required by applicable law and governing Qualified Plan documents.

8. All reports received by the Board of potential or existing conflicts, and all Board action with regard to determining the existence of a conflict of interest, notifying the Adviser, Participating Insurance Companies and Qualified Plans of a conflict, and determining whether any proposed action adequately remedies a conflict, will be properly recorded in the minutes of the appropriate Board or other appropriate records, and such minutes or other records shall be made available to the Commission upon request.

9. Each Insurance Products Fund will notify all Participating Insurance Companies that separate account prospectus disclosure regarding potential risks of mixed and shared funding may be appropriate. Each Insurance Products Fund will disclose in its prospectus that: (a) shares of the Insurance Products Fund may be offered to insurance company separate accounts which fund both annuity and life

insurance contracts, and to Qualified Plans; (b) because of differences of tax treatment and other considerations, the interests of various contract owners participating in the Insurance Products Funds and the interests of Qualified Plans investing in the Insurance Products Funds may conflict; and (c) the Board will monitor its respective Insurance Products Fund for any material conflicts of interest and determine what action, if any, should be taken.

10. Each Insurance Products Fund will comply with all provisions of the 1940 Act requiring voting by shareholders (which, for these purposes, shall be the persons having a voting interest in the shares of the Insurance Products Fund), and, in particular, each such Insurance Products Fund will either provide for annual meetings (except to the extent that the Commission may interpret Section 16 of the 1940 Act not to require such meetings) or comply with Section 16(c) of the 1940 Act), as well as with Sections 16(a) and, if applicable, Section 16(b) of the 1940 Act. Further, each Insurance Products Fund will act in accordance with the Commission's interpretation of the requirements of Section 16(a) with respect to periodic elections of directors (or trustees) and with whatever rules the Commission may promulgate with respect thereto.

11. If and to the extent Rule 6e-2 and Rule 6e-3(T) are amended (or if Rule 6e-3 under the 1940 Act is adopted) to provide exemptive relief from any provisions of the 1940 Act or the rules thereunder with respect to mixed and shared funding on terms and conditions materially different from any exemptions granted in the order requested by Applicants, then the Insurance Products Funds and/or the Participating Insurance Companies, as appropriate, shall take such steps as may be necessary to comply with Rule 6e-2 and Rule 6e-3(T), as amended, and Rule 6e-3, as adopted, to the extent such rules are applicable.

12. No less than annually, the Adviser, the Participating Insurance Companies and Qualified Plans shall submit to the Boards such reports, materials or data as the Boards may reasonably request so that the Boards may carry out fully the obligations imposed upon them by these stated conditions. Such reports, materials, and data shall be submitted more frequently if deemed appropriate by the applicable Boards. The obligations of the Adviser, the Participating Insurance Companies and Qualified Plans to provide these reports, materials, and data to the Boards when it so reasonably requests,

shall be a contractual obligation of the Adviser, the Participating Insurance Companies and Qualified Plans under the agreements governing their participation in the Insurance Products Funds.

13. If a Qualified Plan becomes an owner of 10% or more of the assets of an Insurance Products Fund, such Qualified Plan will execute a fund participation agreement with the applicable Insurance Products Fund including the conditions set forth herein to the extent applicable. A Qualified Plan will execute an application containing an acknowledgment of this condition upon such Qualified Plan's initial purchase of the shares of the Insurance Products Fund.

#### Conclusion

For the reasons stated above, Applicants state that the requested exemptions, in accordance with the standards of Section 6(c), are appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the 1940 Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

*Deputy Secretary.*

[FR Doc. 96-5046 Filed 3-4-96; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-36896; File No. SR-CBOE-96-05]

#### Self-Regulation Organizations; Notice of Filing of Proposed Rule Change by the Chicago Board Options Exchange, Inc., Relating to Limitation of Liability of Index Reporting Authorities

February 27, 1996.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on February 7, 1996, the Chicago Board Options Exchange, Inc. ("CBOE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

<sup>1</sup> 15 U.S.C. § 78s(b)(1) (1988).

<sup>2</sup> 17 CFR 240.19b-4 (1994).

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the IProposed Rule Change

The CBOE proposes to amend Exchange Rule 24.14, which provides for disclaimers of liability on behalf of designated index reporting authorities.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CBOE included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The CBOE has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

##### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

##### 1. Purpose

The purpose of the proposed rule change is to amend Exchange Rule 24.14, which in its present form contains four separate disclaimers of liability on behalf of four different index reporting authorities.<sup>3</sup> Index reporting authorities provide index values to the Exchange that serve as the basis for the various classes of index options listed and traded on the Exchange. Pursuant to the terms of the Exchange's contracts with certain index reporting authorities, the Exchange has agreed to include these specific liability disclaimers in its rules. Although the substance of each of these disclaimers is the same, they differ somewhat in their language, as reflected in the four paragraphs of existing Exchange Rule 24.14. The proposed rule change would combine the four existing disclaimers in a single paragraph in order to eliminate editorial differences among them, and add the CBOE and any other designated index reporting authorities as persons entitled to the benefit of the disclaimer.

##### 2. Statutory Basis

The CBOE believes that the proposed rule change is consistent with Section 6(b) of the Act in general, and with Section 6(b)(5) in particular,<sup>4</sup> in that by

<sup>3</sup> In Exchange Rule 24.1(h), the CBOE defines the term "reporting authority" in respect of a particular index as the institution or reporting service designated by the Exchange as the official source for calculating the level of the index from the reported prices of the underlying securities that are the basis of the index and reporting such level.

<sup>4</sup> 15 U.S.C. § 78f(b)(5) (1988).



retaining and clarifying existing disclaimers of liability that have been found to satisfy statutory standards, the proposed rule change will improve the basis on which index options are listed and traded on the CBOE, which, in turn, will serve to promote just and equitable principles of trade as well as to protect investors and the public interest.

#### *B. Self-Regulatory Organization's Statement on Burden on Competition*

The CBOE does not believe that the proposed rule change will impose any inappropriate burden on competition.

#### *C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others*

No written comments were solicited or received with respect to the proposed rule change.

#### **III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Within 35 days of the publication of this notice in the Federal Register or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which the CBOE consents, the Commission will:

A. By order approve the proposed rule change, or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

#### **IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. § 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of such filing also will be available for inspection and copying at the principal office of the CBOE. All submissions

should refer to File No. SR-CBOE-96-05 and should be submitted by March 26, 1996.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.<sup>5</sup>

Margaret H. McFarland,

*Deputy Secretary.*

[FR Doc. 96-5044 Filed 3-4-96; 8:45 am]

BILLING CODE 8010-01-M

**[Release No. 34-36894; File No. SR-CBOE-96-06]**

#### **Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change by the Chicago Board Options Exchange, Inc., Relating to Arbitration Procedures**

February 27, 1996.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on February 7, 1996, the Chicago Board Options Exchange, Inc. ("CBOE" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is approving this proposal on an accelerated basis.

#### **I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change**

Currently, paragraph (c), "Pre-Hearing Exchange," of CBOE Rule 18.22, "General Provisions Governing Pre-hearing Proceeding," provides that, at least ten calendar days prior to the first hearing date, all parties must serve on each other copies of documents in their possession that they intend to present at the hearing and identify witnesses they intend to present at the hearing. The CBOE proposes to amend Exchange Rule 18.22(c) to provide that at least 20 calendar days prior to the first hearing date: (1) the parties shall serve on each other copies of documents in their possession that they intend to present at the hearing; (2) the parties may provide each other and the Director of Arbitration with a list of documents that have already been produced pursuant to other provisions of CBOE Rule 18.22 in lieu of the actual documents; and (3) the parties shall serve on each other and on the Director of Arbitration a list identifying witnesses they intend to present at the hearing by name, address,

and business affiliation. In addition, the CBOE proposes to amend CBOE Rule 18.22(g), "Power to Direct Appearances and Production of Documents," to clarify that arbitrators may direct the appearance of any CBOE member without resort to the subpoena process.

The text of the proposal is available at the Office of the Secretary, CBOE and at the Commission.

#### **II. Self-Regulatory Organization's Statement of the Purpose of and Statutory Basis for, the Proposed Rule Change**

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

#### *A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

The purpose of the proposal is to amend CBOE Rule 18.22(c) to conform the Exchange's rule to Section 20(c) of the Uniform Code of Arbitration ("Uniform Code"), as amended by the Securities Industry Conference on Arbitration ("SICA").<sup>1</sup> In addition, the CBOE proposes to amend CBOE 18.22(g) to clarify that arbitrators have power over members to direct appearance and produce documents without resort to the subpoena process. According to the CBOE, the proposed changes to CBOE Rule 18.22(c) have been adopted by the National Association of Securities Dealers ("NASD") and the New York Stock Exchange ("NYSE").<sup>2</sup>

Currently, CBOE Rule 18.22(c) requires the parties, at least ten calendar days prior to the first scheduled hearing date, to serve each other with any documents in their possession and to identify witnesses they intend to present at the hearing. The proposed amendment to Exchange Rule 18.22(c) allows parties to provide a list of documents that have been produced

<sup>1</sup> CBOE Rule 18.22(c) corresponds to SICA Uniform Code Section 20(c) (as amended January 7, 1993, and October 21, 1994).

<sup>2</sup> See Securities Exchange Act Release Nos. 36222 (September 13, 1995) 60 FR 48576 (September 19, 1995) (order approving File No. SR-NYSE-95-25); and 35525 (March 23, 1995), 60 FR 16219 (March 29, 1995) (order approving File No. SR-NASD-95-05) ("Arbitration Approval Orders").

<sup>5</sup> 17 CFR 200.30-3(a)(12) (1994).

previously to the other side, in lieu of producing the same documents again. The CBOE believes that the proposed change will provide for more efficient pre-hearing exchanges by not requiring the parties to again exchange those documents that have been produced previously. The proposal also requires that the witness list include the address and business affiliation of the witnesses identified. This will allow the parties to receive advance notice as to the background of witnesses and the location of nonparty witnesses. Finally, the proposed amendment to CBOE Rule 18.22(c) requires prehearing exchanges to occur 20 days in advance of the hearing, instead of ten days, as is presently required. The Exchange believes that this part of the proposal will serve to provide the parties with sufficient time to organize and present their cases in an efficient manner.

In addition, the CBOE proposes to amend CBOE Rule 18.22(g). Currently, CBOE Rule 18.22(g) empowers arbitrators, without resorting to the subpoena process, to direct the appearance of employees of members and associated persons of members, and order those persons, as well as member organizations, to produce records in their control. The proposed change to paragraph (g) clarifies that arbitrators have the same power over members to direct appearances and produce documents without resort to the subpoena process.

By conforming the rules of the Exchange to those of other self-regulatory organizations ("SROs"), the CBOE believes that the proposed rule change is consistent with the Section 6(b) of the Act, in general, and furthers the objectives of Section 6(b)(5), in particular, in that it is designed to promote just and equitable principles of trade and to protect investors and the public interest by improving the administration of an impartial arbitration forum for the resolution of disputes between members, persons associated with members, and public investors.

*(B) Self-Regulatory Organization's Statement on Burden on Competition*

The CBOE does not believe that the proposed rule change will impose any burden on competition.

*(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others*

No written comments were solicited or received with respect to the proposed rule change.

**III. Commission's Findings and Order Granting Accelerated Approval of the Proposed Rule Change**

The CBOE has requested that the proposed rule change be given accelerated effectiveness pursuant to Section 19(b)(2) of the Act because the proposed amendments to CBOE Rule 18.22(c) have been proposed previously by other SROs and approved by the Commission.<sup>3</sup> The Exchange believes good cause exists for approving the proposal on an accelerated basis in order to ensure and promote uniformity in the rules governing the administration of arbitration facilities offered by the SROs.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, the requirements of Section 6(b)(5) of the Act<sup>4</sup> in that the proposal is designed to promote just and equitable principles of trade, to prevent unfair discrimination between customers, issuers, brokers, or dealers, and, in general, to protect investors and the public interest. The CBOE proposes to amend Exchange Rule 18.22(c) to allow parties to: (1) Provide a list of documents that have been produced previously to the other side, instead of providing the actual documents; (2) require the list identifying witnesses to include the address and business affiliation of the witnesses listed; and (3) require pre-hearing exchanges of documents and the list of documents previously produced to occur 20 days in advance of the hearing, instead of ten days, as is presently required. The Commission believes that the proposed amendments to CBOE Rule 18.22(c) should increase the efficiency of the arbitration process by eliminating duplicative prehearing documents exchanges. In addition, the Commission believes that the proposed amendments should: (1) Assist parties in the process of preparing and organizing their cases by providing them with advance notice regarding the background of witnesses and the location of nonparty witnesses; (2) reduce the number of instances of surprise; and (3) provide parties with a more reasonable time frame in which to address last minute discovery requests.

The Commission finds that the proposed amendment to CBOE Rule 18.22(g) is designed to protect investors and the public interest by clarifying the power of arbitrators to direct the

appearance of CBOE members, as well as persons employed by or associated with CBOE members, without resort to the subpoena process.

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice thereof in the Federal Register because the proposed amendments to Exchange Rule 18.22(c) are identical to rules adopted previously by other SROs.<sup>5</sup> The Commission notes that the proposals by the NYSE and the NASD were published for comment in the Federal Register and that no comments were received concerning their proposals. The Commission does not believe that the CBOE's amendments to Exchange Rule 18.22(c) raise new regulatory issues. In addition, the Commission finds good cause for approving the CBOE's amendment to Exchange Rule 18.22(g) because the amendment clarifies the power of arbitrators to direct the appearance of Exchange members without resort to the subpoena process.

**IV. Solicitation of Comments**

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, N.W., Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by March 26, 1996.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,<sup>6</sup> that the proposed rule change (File No. SR-CBOE-96-06), is approved.

<sup>3</sup> See Arbitration Approval Orders, *supra* note 2.

<sup>4</sup> 15 U.S.C. § 78f(b)(5) (1982).

<sup>5</sup> See Arbitration Approval Orders, *supra* note 2.

<sup>6</sup> 15 U.S.C. § 78s(b)(2) (1982).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.<sup>7</sup>

Margaret H. McFarland,  
*Deputy Secretary.*

[FR Doc. 96-5045 Filed 3-4-96; 8:45 am]

BILLING CODE 8010-01-M

## **SMALL BUSINESS ADMINISTRATION**

### **Augusta District Advisory Council Public Meeting**

The U.S. Small Business Administration, Augusta District Advisory Council will hold a public meeting on Thursday, April 4, 1996 at 9:00 am at Androscoggin Valley Council of Governments, 125 Manley Road, Auburn, Maine, to discuss matters as may be presented by members, staff of the U.S. Small Business Administration, or others present.

For further information, write or call Mr. Roy Perry, District Director, U.S. Small Business Administration, 40 Western Avenue, Augusta, Maine 04330, (207) 622-8242.

Dated: February 27, 1996.

Bill Combs,

*Associate Administrator for Office of Communication and Public Liaison.*

[FR Doc. 96-5032 Filed 3-4-96; 8:45 am]

BILLING CODE 8025-01-P

## **DEPARTMENT OF TRANSPORTATION**

### **Coast Guard**

[CGD 96-007]

### **Civil GPS Service Interface Committee Meeting Announcement**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Notice of meeting.

**SUMMARY:** The Civil Global Positioning System (GPS) Service Interface Committee (CGSIC) will meet to discuss various issues. Agenda items include GPS Policy, interference problems, and status of GPS initiatives. This meeting is open to the public.

**DATES:** The General Committee meeting will meet on 19-20 March 1996, from 8:30 a.m. to 5:50 p.m. daily. The Subcommittee will meet on 21 March 1996.

**ADDRESSES:** The meeting will be held at the DoubleTree Hotel, 7801 Leesburg Pike, Falls Church, VA.

**FOR FURTHER INFORMATION CONTACT:** Rebecca Casswell, United States Coast Guard Navigation Center, at (703) 313-

5930 or FAX at (703) 313-5805. The meeting agenda is available to the Electronic Bulletin Board System (BBS) at the Navigation Information Service (NIS) in Alexandria, Virginia, at (703) 313-5910. For information on the BBS, call the watchstander of NIS at (703) 313-5900.

**SUPPLEMENTARY INFORMATION:** The CGSIC was formed to exchange GPS information and to identify GPS issues and needs that affect the nonmilitary user (e.g. navigation, timing, and positioning). This is done in support of the DOT's Civil GPS Service Program and as a function of the Assistant Secretary for Transportation Policy's outreach program to the civil GPS Service user community. The CGSIC is open to representatives from relevant private, government, and industry user groups, both U.S. and international. The meeting is chaired by the Department of Transportation's Radionavigation Policy and Planning Staff Chief.

Dated: February 28, 1996.

Rudy K. Peschel,

*Rear Admiral, U.S. Coast Guard Chief, Office of Navigation Safety and Waterway Services.*

[FR Doc. 96-5058 Filed 3-4-96; 8:45 am]

BILLING CODE 4910-14-M

[CGD 96-009]

### **Commerical Fishing Industry Vessel Advisory Committee (CFIVAC) Meeting**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Notice of meeting.

**SUMMARY:** CFIVAC will meet to discuss various issues relating to fishing industry vessel safety. The meetings are open to the public.

**DATES:** The CFIVAC meeting will be held on Wednesday and Thursday, April 24-25, 1996, from 8:30 a.m. to 5 p.m. daily. Persons wishing to make oral presentations or provide written material during the meeting should notify the Executive Director, listed below under **ADDRESSES**, on or before April 15, 1996.

**ADDRESSES:** The CFIVAC meeting will be held at the Stouffer Madison Renaissance Hotel, 515 Madison Street, Seattle, Washington 98104. Written material should be submitted to CDR Adan D. Guerrero, Executive Director, Commandant (G-MOS-2), U.S. Coast Guard, 2100 Second Street SW., Washington, DC 20593-0001.

**FOR FURTHER INFORMATION CONTACT:** CDR Adan D. Guerrero, Executive Director, or LCDR Mark D. Bobal, Assistant to the Executive Director, Commandant (G-MOS-2), U.S. Coast

Guard, 2100 Second Street SW., Washington, DC 20593-0001, telephone (202) 267-1181, fax (202) 267-4570.

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is given pursuant to the Federal Advisory Committee Act, 5 U.S.C. App. 2 § 1 et seq. The agenda for the CFIVAC meeting will include discussion of the following topics:

(1) Seek committee input on implementation of the Convention on Standards of Training, Certification and Watchkeeping for Fishing Vessels, (STCW-F);

(2) Committee discussion on Prevention Through People (PTP) Initiatives and how this program can update NVIC 5-86 dealing with voluntary standards for commercial fishing industry vessels;

(3) Committee discussion on fires in refrigerated holds on fish processing vessels;

(4) Committee discussion on major conversion issues for commercial fishing industry vessels;

(5) Sub-Committee working session on stability standards for commercial fishing industry vessels;

(6) Sub-Committee working sessions on updating the voluntary standards of U.S. uninspected commercial fishing vessels found in Navigational and Vessel Inspection Circular, (NVIC), 5-86.

Attendance at the meeting is open to the public. With advance notice, and at the Chairman discretion, members of the public may make oral presentations at the meeting. Persons wishing to make oral presentations should notify the Executive Director, listed above under "ADDRESSES", no later than April 22, 1996. Written material may be submitted at any time for presentation to CFIVAC.

However, to ensure advance distribution to each member, persons submitting written material are asked to provide 20 copies to the Executive Director no later than April 15, 1996.

Dated: February 28, 1996.

Joseph J. Angelo,

*Director for Standards, Office of Marine Safety, Security and Environmental Protection.*

[FR Doc. 96-5059 Filed 3-4-96; 8:45 am]

BILLING CODE 4910-14-M

[CGD 96-008]

### **National Offshore Safety Advisory Committee (NOSAC), Meeting**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Notice of meeting.

<sup>7</sup> 17 CFR 200.30-3(a)(12) (1995)

**SUMMARY:** NOSAC will meet to discuss various issues relating to offshore safety. The meeting will be open to the public.

**DATES:** The NOSAC meeting will be held on Friday, March 29, 1996, from 9 a.m. to 3:30 p.m. Persons wishing to make oral presentations or provide written material during the meeting should notify the Executive Director, listed below under **ADDRESSES**, on or before March 15, 1996.

**ADDRESSES:** The NOSAC meeting will be held in Rooms 4436/4440, of the NASSIF Building, 400 7th Street, SW., Washington, DC. Written material should be sent to Captain R. L. Skewes, Executive Director, Commandant (G-MOS), U.S. Coast Guard, 2100 Second Street SW., Washington, DC 20593-0001.

**FOR FURTHER INFORMATION CONTACT:** Captain R. L. Skewes, Executive Director, or Mr. Jim Magill, Assistant to the Executive Director, Commandant (G-MOS-2), U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593-0001, telephone (202) 267-0214, fax (202) 267-4570.

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is given pursuant to the Federal Advisory Committee Act, 5 U.S.C. App. The agenda for the NOSAC will include discussion of the following topics:

- (1) Revision of Subchapter "N";
- (2) Implementation of Subchapter "L" on Offshore Supply Vessels (OSVs) and Liftboats;
- (3) Establishment of Pipeline-free Anchorages for Mobile Offshore Drilling Units (MODUs), Liftboats and Vessels;
- (4) Implementation of "Prevention Through People" in the Offshore Industry;
- (5) Coordination of International Safety Management Code and Safety and Environmental Management Program for MODUs and platforms;
- (6) International Maritime Organization (IMO)/International Organization of Standardization Issues;
- (7) IMO Code of Safe Practice for OSVs.

Attendance at the meeting is open to the public. With advance notice, and at the Chairman's discretion, members of the public may make oral presentations during the meeting. Persons wishing to make oral presentations should notify the Executive Director, listed above under **ADDRESSES**, no later than March 28, 1996. Written material may be submitted at any time for presentation to NOSAC. However, to ensure advance distribution to each Committee member, persons submitting written material are asked to provide 20 copies to the

Executive Director no later than March 15, 1996.

Dated: February 28, 1996.  
Joseph J. Angelo,  
*Director for Standards, Office of Marine Safety, Security and Environmental Protection.*  
[FR Doc. 96-5061 Filed 3-4-96; 8:45 am]  
**BILLING CODE 4910-14-M**

## Federal Aviation Administration

### Emergency cease and desist order and notice of enforcement policy

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Emergency Cease and Desist Order and Notice of Enforcement Policy.

**SUMMARY:** This order and policy statement is necessary to address safety concerns arising from the interception and destruction of two U.S. civilian aircraft in international airspace north of Cuba and the unauthorized operation of U.S. aircraft in Cuban territorial airspace.

**EFFECTIVE DATE:** February 29, 1996.

**FOR FURTHER INFORMATION CONTACT:** Peter J. Lynch, Assistant Chief Counsel for Enforcement, Enforcement Division, Office of the Chief Counsel, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-9956.

#### SUPPLEMENTARY INFORMATION:

##### Background

On February 24, 1996, Cuban military aircraft intercepted and destroyed two unarmed U.S.-registered civilian aircraft in international airspace north of Cuba. These aircraft posed no credible threat to Cuba's security. The President directed his Administration to take immediate steps in response to the Cuban Government's actions. Among other steps, the United States sought condemnation of Cuba's actions by the United Nations Security Council and the International Civil Aviation Organization. The President also suspended all commercial charter flights to Cuba indefinitely.

On February 27, 1996, the United Nations Security Council strongly deplored the destruction of the two civil aircraft by the Cuban air force, and requested that the International Civil Aviation Organization investigate the incident in its entirety and reports its findings to the Security Council as soon as possible.

Unauthorized operation of U.S.-registered civil aircraft in Cuban territorial airspace is prohibited by the

Federal Aviation Regulations. The United States Government has issued statements warning of the serious consequences that could occur should any person conduct such operations.

Notwithstanding such advice and warnings of the United States Government and the unlawfulness of the conduct, operations without authorization in Cuban territorial airspace have occurred.

Based on the circumstance described above, I find that an emergency exists relating to safety in air commerce, and that there is an immediate need to take action for reasons of safety of flight in the vicinity of the Florida Straits and to ensure against the unauthorized entry of U.S. civil aircraft into Cuban territorial airspace. Unauthorized operation of U.S.-registered civil aircraft into the territorial airspace of the Republic of Cuba is prohibited.

#### Statement of Policy

Now, therefore, it is ordered that any person holding a U.S. airman certificate and/or operating U.S.-registered civil aircraft who has conducted unauthorized operations within Cuban territorial airspace Cease and desist from this unlawful activity.

It is further ordered that all persons holding U.S. airman certificates and/or operating U.S.-registered civil aircraft comply with the Federal Aviation Regulations prohibiting unauthorized operation within Cuban territorial airspace.

#### Enforcement Policy

Take notice that, effective immediately, any person who makes unauthorized entry into the territorial airspace of the Republic of Cuba in violation of the Federal Aviation Regulations will be subject to enforcement action to the maximum extent permitted by law, including, but not limited to the following: Immediate revocation of pilot certificate; maximum civil penalties; seizure of aircraft involved in such a violation; and appropriate judicial remedies.

(Authority: 49 U.S.C. Sections 40113(a), 44709, 46105(c), 46301, 46304(b), 46106, and 46107.)

Further, any person who operates or attempts to operate an aircraft after pilot certificate revocation, or otherwise without a valid airman certificate, is subject to criminal penalties of up to 3 years in prison, and/or fines (49 U.S.C. Section 46306(b)(7)).

Issued in Washington, DC, on February 29, 1996.

David R. Hinson,  
Administrator.

[FR Doc. 96-5183 Filed 3-1-96; 10:22 am]

BILLING CODE 4910-13-M

## Federal Railroad Administration

[FRA Emergency Order No. 20, Notice No. 2]

### **Commuter and Intercity Passenger Railroads, Including Public Authorities Providing Passenger Service, and Affected Freight Railroads; Clarification of Emergency Order Requiring Enhanced Operating Rules and Plans for Ensuring the Safety of Passengers Occupying the Leading Car of a Train With Appropriate Amendments**

#### Introduction

On February 20, 1996, the Federal Railroad Administration (FRA) issued Emergency Order No. 20 (Notice No. 1). The order required prompt action to immediately enhance passenger train operating rules and emergency egress and to develop a more comprehensive interim system safety plan addressing cab car forward and multiple unit (MU) operations that do not have either cab signal, automatic train stop, or automatic train control systems. Subsequent to issuance of the order, FRA and the Federal Transit Administration (FTA) recognized that the original order's safety measures, while establishing requirements to abate the safety risks at issue, would benefit from refinements increasing their effectiveness. Three aspects of the original order are being refined in this notice. FRA is: (1) More sharply focusing and strengthening the provisions relating to the delay in block rule; (2) tailoring the signal calling provisions to reflect more diverse operating situations; and (3) providing more detailed guidance on the emergency egress sampling provision. FRA is also clarifying measures that apply to defective cab signal, automatic train stop (ATS) and automatic train control (ATC).

Emergency Order No. 20 generally applies to commuter and intercity passenger railroads using push-pull and MU operations where cab signal, ATS, or ATC is not in operation and trains are operating in excess of 30 miles per hour. Although enroute failures are rare events, if cab signals, ATS or ATC fail, the relevant safety measures of this order apply. The only exception would be when cab signal, ATS or ATC fail on

track that is not governed by wayside signals. In those instances, adherence to existing federal standards and applicable operating rules provide a comparable level of safety. It is important to note, however, that railroads are not expected to conduct efficiency testing when cab signal, ATS, or ATC is the normal method of operation and there is an occasional failure. Therefore, railroads are not expected to interfere with normal operation of the cab signal, ATS, or ATC systems for such efficiency testing. All changes and the clarification addressed above reflect discussions that FRA and FTA held with the commuter and intercity railroads subsequent to issuance of the order.

#### *(1) Delayed in Block*

The original order required application of the delay-in-block provisions regardless of the train's location on the railroad although, in the relevant accidents that formed the basis for the order, the trains involved were operating in a block immediately preceding an interlocking or controlled point. Additionally, the original order provided no maximum speed for delayed-in-block movements other than that provided in relevant railroad rules. The FRA's refined approach will limit the order's applicability to blocks immediately preceding interlockings and controlled points and require that the train reduce speed in accordance with applicable operating rules, but in no case may speed exceed 40 miles per hour. FRA established the maximum speed of 40 miles per hour in accordance with the reduced speed imposed under its regulations addressing failure of cab signal, ATS, or ATC devices (see 49 CFR 236.567, 236.811). This will more clearly focus the rule on the situations intended to be addressed by the original order and ensure that the maximum reduced speed permitted where the rule applies is standardized and is based on a known standard. In other words, the maximum speed where the rule applies will be 40 miles per hour or less, depending upon the railroad's rules. FRA is also strengthening the delay-in-block rule by adding a measure requiring that appropriate signs be installed at each affected signal and at the departure end of stations. This will prevent confusion as to where the rule applies.

#### *(2) Signal Calling*

The modification to the signal calling provision reflects the reality that designated crew members will be positioned in varying locations when receiving the verbal communication

identifying the signal indication. Although the initial version of the order specified a particular location on the train (i.e. in a trailing unit or car), the underlying safety concern can be satisfied by having the crew member receive and acknowledge the communication regardless of the responder's physical location on the train.

#### *(3) Emergency Egress*

The original order required but did not set parameters for testing a representative sample of emergency exits. The alteration to the emergency egress provisions requires that sampling of emergency window exits be conducted in conformity with either of two alternate methods commonly recognized for such efforts. This modification provides a degree of uniformity industry wide. These methods require sampling meeting a 95 percent confidence level that all emergency window exits operate properly (i.e., the methods do not accept a defect rate of 5 percent). Although the original order would have required testing all exits on a specific series or type of car if one such car had a defective window exit, the amended order permits the use of these commonly accepted sampling techniques to determine how many additional windows in test. In general, these principles require that the greater the percentage of windows initially found defective, the greater the percentage of windows that will have to be tested.

In addition, FRA has modified the emergency egress portion of the order to clarify that the exterior marking requirement applies to those windows that may be employed for access by emergency responders, which may be windows other than, or in addition to, those designed for emergency egress for passengers. In addition, FRA has modified the interim system safety plan portion of the order to require discussion of the railroad's programs and plans for liaison with and training of emergency responders with respect to emergency access to passengers. The original order required discussion only of methods used to inform passengers of the location and method of emergency exits.

#### Finding and Order

FRA concludes that certain current conditions and practices on commuter and intercity passenger railroads pose an imminent and unacceptable threat to public and employee safety. Of greatest concern are push-pull and MU operations lacking the protection

provided by cab signal, automatic train stop, or automatic train control systems. Based on the matters discussed in Notice No. 1 of this order, I found that the unsafe conditions discussed there create an emergency situation involving a hazard of death or injury to persons. While I continue to find an emergency situation to exist, I have concluded that certain modifications to the order are necessary. For the convenience of those subject to this order, I have set forth here all of its terms, as amended. Accordingly, pursuant to the authority of 49 U.S.C. § 20104, delegated to me by the Secretary of Transportation (49 CFR § 1.49), it is hereby ordered that each commuter and intercity passenger railroad, and any other entity (e.g., freight railroads over whose lines affected passenger operations are conducted) whose actions are necessary to effectuate the directives in this order, take the following actions:

### (1) *Delayed-in-Block Rule*

Note: This rule applies to all push-pull and MU operations unless cab signal, automatic train stop, or automatic train control is in operation, speeds do not exceed 30 m.p.h., or within yard or terminal limits as specified for this purpose by the railroad.

- (A) On March 4, 1996, at 12:01 a.m., have in effect, publish in its code of operating rules, and comply with a rule that requires: If a passenger train operating in the block immediately preceding an interlocking or controlled point stops for any reason, or its speed is reduced below 10 m.p.h., the train shall proceed under the reduced speed set forth in applicable operating rules governing such circumstances and be prepared to stop before passing the next signal. In no event shall this reduced speed exceed 40 m.p.h., although lower speeds are permissible. The train must maintain the prescribed reduced speed until the next wayside signal is clearly visible and that signal displays a proceed indication. A copy of the rule will be provided to the FRA Office of Safety Assurance and Compliance in care of James T. Schultz, Staff Director, Operating Practices.

- (B) Within 30 days of issuance of the railroad's rule, a railroad operating supervisor shall personally contact each engineer and conductor in passenger service and inform them in a face-to-face meeting of the requirements of that rule. Such briefing shall be documented and such documentation shall be available for FRA review upon request, including date, time, location, crew members contacted, and supervisor making the contact.

- (C) Within 60 days of issuance of the railroad's rule, each engineer/

conductor in such passenger service shall receive an unannounced operational ("efficiency") test on the rule which requires a full stop at the signal ahead; and, within 90 days of rule publication, an on-board operational monitoring ride shall be conducted by an operating supervisor of the railroad to ensure a complete understanding of rule provisions. Such tests and operational monitoring checks shall be documented and such documentation shall be available for FRA review upon request, including date, time, location, crew members involved, and supervisor making the test/monitoring ride.

- (D) The railroad's program of operational tests and inspections under 49 CFR Part 217 shall be revised as necessary to include this rule, and shall specifically include a minimum of two such tests per year for each passenger engineer.

- (E) Within 30 days of issuance of the railroad's rule, an appropriate qualifying appurtenance shall be affixed to each signal governing the approach to an interlocking or controlled point signal to serve as a visual reminder to the engineer. Appropriate signage shall be displayed at the departure end of passenger stations located in the block immediately preceding interlockings or controlled points.

### (2) *Crew Communications Rule*

Note: This rule applies to all push-pull and MU operations unless cab signal, automatic train stop, or automatic train control is in operation, speeds do not exceed 30 m.p.h., or within yard or terminal limits as specified for this purpose by the railroad.

- (A) On March 4, 1996, at 12:01 a.m., have in effect, publish in its operating rules, and comply with a rule that requires: A crew member located in the operating cab of a controlling locomotive, cab car, or MU car, shall have means to communicate orally and shall communicate the indication and location of each wayside signal affecting the movement of the train as soon as the signal becomes visible, for all signals which require either (1) that the train be prepared to stop at the next wayside signal, or (2) that the train be prepared to pass the next wayside signal at restricted speed. In multiple track territory, the crew member shall include the affected track number. A copy of the rule shall be provided to the FRA Office of Safety Assurance and Compliance in care of James T. Schultz, Staff Director, Operating Practices.

- (B) A designated crew member shall immediately acknowledge the transmission, and confirm the information to the crew member(s) on the controlling locomotive by repeating

the message. If the designated crew member fails to acknowledge the communication, the engineer must ascertain at the next scheduled stop why the message is not being confirmed. If necessary due to radio equipment failure, alternative means shall be established by the operating crew (e.g., via intercom, cellular telephone, etc.) to accomplish the procedure.

- (C) If the engineer fails to control the train movement in accordance with either a wayside signal indication or other restrictions imposed upon the train, the designated crew member shall at once communicate with and caution the engineer regarding the restriction, and, if necessary, take appropriate action to ensure the safety of the train, including stopping the movement if appropriate.

- (D) Within 30 days of the issuance of the railroad's rule, a railroad operating supervisor shall personally contact each engineer and conductor in passenger service and inform them in a face-to-face meeting of the requirements of this rule. Such briefing shall be documented and such documentation shall be available for FRA review upon request, including date, time, location, crew members contacted, and supervisor making the contact.

- (E) Within 60 days of the issuance of the railroad's rule, each engineer/conductor in such passenger service shall receive an unannounced operational "efficiency" test on the rule; and, within 90 days of rule publication, an on-board operational monitoring ride shall be conducted by an operating supervisor of the railroad to ensure a complete understanding of rule provisions. Such tests and operational monitoring checks shall be documented and such documentation shall be available for FRA review upon request, including date, time, location, crew members involved, and supervisor making the test/monitoring ride.

- (F) The railroad's program of operational tests and inspections under 49 CFR Part 217 shall be revised as necessary to include this rule, and shall specifically include a minimum of two such tests per year for each passenger engineer.

### (3) *Emergency Egress: Marking and Inspecting Exits*

- (A) No later than April 20, 1996, ensure that each emergency exit location is marked inside the car for passenger and crew information. Markings for egress from inside the car shall be accompanied by clear and legible instructions for operation of the exit. Also, clear markings shall also be provided on the exterior of each car

indicating which windows may be employed for access by emergency responders. All such markings must be clearly visible and legible at egress locations. This paragraph does not require action where reasonably conspicuous and fully legible markings and instructions already exist.

- (B) Immediately begin, and by April 20 complete, a program to test a representative sample of emergency window exits on cars in its fleets to verify proper operation. Sampling must be conducted to meet a 95% confidence level and in accordance with Military Standard MIL-STD-105(D) Sampling for Attributes or American National Standards Institute ANSI-ASQC Z1.4-1993 Sampling Procedures for Inspections by Attributes. Defective units will be repaired before the car is returned to service. Railroads must report to FRA when such action is necessary, and shall include a timetable for window inspection and replacement on the car series to remedy the problem in the most expeditious manner.

- (C) Records of the date, car number, and verification of proper exit operation shall be maintained and available for FRA review upon request. Each railroad shall also verify emergency exit operation as part of routine vehicle maintenance cycles.

#### (4) *Interim System Safety Plans*

Each authority operating or contracting for the operation of push-pull, EMU or DMU service (including Amtrak) shall, not later than April 5, 1996, submit to FRA an interim system safety plan for the purpose of enhancing the safety of such operations. In developing such plans, the authority shall provide opportunity for the riding public and designated representatives of railroad employees to comment on proposed actions that may affect the quality of service, including passenger safety.

The plan shall address the following hazards associated with passenger occupancy of lead units:

- Train-to-train collisions.
- Derailments giving rise to the hazard of impact with fixed structures.
- Collisions with heavy vehicles at highway-rail crossings.

The plan shall take into consideration the overall safety of all passengers and crew members and shall, at a minimum, address the following opportunities for risk reduction:

- (A) *Use of cab car/MU car.* The authority shall specify the circumstances under which occupancy of a cab or MU car in the lead position is permitted, by route and train assignment. The authority shall propose

or report appropriate modifications in such practices, taking into consideration service needs (e.g., equipment capacity, passenger loadings) and safety issues (e.g., train densities, method of operation, availability of cab signals and automatic control, issues related to standing passengers, grade crossing exposure, and other relevant factors).

- (B) *Operating rules.* The authority shall review railroad operating rules and practices pertinent to the hazards listed above to determine if further enhancements in safety are warranted and advise FRA as to what action is necessary to enhance the level of safety. Changes in existing rules shall be specified. In conducting this review, the operating authority shall analyze the measures imposed in sections 1 and 2 of this order and may propose alternative approaches that ensure the same enhancements in safety associated with those measures.

- (C) *Adverse conditions.* In conducting the review of railroad operating rules and practices, consideration shall be given to adverse or unusual operating conditions such as weather (e.g., fog, heavy rain or snow, flooding, etc.).

- (D) *Short-term technology enhancements.* The authority shall consider short-term enhancements in technology that may improve the safety of train operations, such as use of alerting devices, equipping of additional locomotives with cab signal/ATC apparatus (where in effect on the territory), or other available enhancements to enhance engineer performance or provide warning of operation in excess of authority provided by the wayside signal system. In addition, the authority shall consider whether the installation of additional signals on any particular line would appreciably reduce the risk of train collisions.

- (E) *Crew management.* The authority shall review crew management practices in light of contemporary literature regarding shift work and cumulative fatigue to determine if the alertness and performance of employees can be promoted by changes in those practices. Special attention shall be given to the issue of night split shifts.

- (F) *Highway-rail grade crossings.* The authority shall review risks to passengers associated with occupancy of cab or MU cars in the lead while passing over highway-rail crossings, particularly crossings utilized by heavy vehicles and vehicles transporting hazardous materials, and shall address measures that can reduce these risks.

- (G) *Emergency exit notification.* The authority shall review methods it uses, in addition to marking emergency exits,

to inform passengers of the location and operation of those exits, such as flyers dropped on seats, announcements to passengers, explanations on the face of passenger tickets, etc. The authority shall specify any plans it has to increase passenger awareness of the location and operation of emergency exits. The authority shall also discuss its plans for liaison with and training of emergency responders with respect to emergency access to passenger cars.

Upon receipt of plans responsive to the above-reference requirements, the Administrator, in consultation with the FTA Administrator, will determine whether other mandatory action appears necessary to address hazards associated with the subject rail passenger service.

#### Relief

Petitions for special approval to take actions not in accordance with this order may be submitted to the Associate Administrator for Safety, who shall be authorized to dispose of those requests without the necessity of amending this order. A copy of this petition should be submitted to the Docket Clerk, Office of Chief Counsel, Federal Railroad Administration, 400 Seventh Street, S.W., Washington, D.C. 20590.

#### Penalties

Any violation of this order shall subject the person committing the violation to a civil penalty of up to \$20,000. 49 U.S.C. §§ 21301. FRA may, through the Attorney General, also seek injunctive relief to enforce this order. 49 U.S.C. § 20112.

#### Effective Date and Notice to Affected Persons

The amendments to this order shall take effect at 12:01 a.m. on March 4, 1996. The original order would have required the railroad to have its revised operating rules on delay in block and crew communications to be in place by March 2. The additional two days granted here is intended to ensure that it is feasible to revise, issue, and implement the revised rules by Monday, March 4. Other deadlines (i.e., for compliance with the emergency egress and interim system safety plan requirements) are not changed, but actual dates have been inserted to avoid confusion about how to count the days allotted for certain tasks. This notice will be published in the Federal Register as soon as possible. Prior to publication, copies of this notice will be delivered by overnight mail or facsimile to the affected passenger railroads, public authorities, and railroad labor organizations.



## Review

Opportunity for formal review of this Emergency Order will be provided in accordance with 49 U.S.C. § 20104(b) and section 554 of Title 5 of the United States Code. Administrative procedures governing such review are found at 49 CFR Part 211. See 49 CFR §§ 211.47, 211.71, 211.73, 211.75, and 211.77.

Issued in Washington, D.C. on February 29, 1996.

Jolene M. Molitoris,

*Administrator.*

[FR Doc. 96-5216 Filed 3-1-96; 2:06 pm]

BILLING CODE 4910-06-P

## National Highway Traffic Safety Administration

### Announcing the Fourteenth Meeting of the Motor Vehicle Safety Research Advisory Committee

**AGENCY:** National Highway Traffic Safety Administration (NHTSA), DOT.

**ACTION:** Meeting announcement.

**SUMMARY:** This notice announces the fourteenth meeting of the Motor Vehicle Safety Research Advisory Committee (MVSRAAC). The Committee was established in accordance with the provisions of the Federal Advisory Committee Act to obtain independent advice on motor vehicle safety research. Discussions at this meeting will include specific topics in NHTSA's Crashworthiness, Crash Avoidance and Behavioral Research research programs.

**DATE AND TIME:** The meeting is scheduled from 9:00 a.m. to 5:00 p.m. on Wednesday, March 20, 1996.

**ADDRESSES:** The meeting will be held in Room 6244-48 of the U.S. Department of Transportation Building, which is located at 400 Seventh Street, SW., Washington, DC.

**SUPPLEMENTARY INFORMATION:** In May 1987, the Motor Vehicle Safety Research Advisory Committee was established. The purpose of the Committee is to provide an independent source of ideas for motor vehicle safety research. The MVSRAAC will provide information, advice and recommendations to NHTSA on matters relating to motor vehicle safety research, and provide a forum for the development, consideration and communication of motor vehicle safety research, as set forth in the MVSRAAC Charter.

The meeting is open to the public, but attendance may be limited due to space availability. Participation by the public will be determined by the Committee Chairperson.

A public reference file (Number 88-01) has been established to contain the products of the Committee and will be open to the public during the hours of 9:30 a.m. to 4:00 p.m. at the National Highway Traffic Safety Administration's Technical Reference Division in Room 5108 at 400 Seventh Street, SW., Washington, DC 20590, telephone: (202) 366-2768.

**FOR FURTHER INFORMATION CONTACT:** Ms. Barbara Coleman, Office of Research and Development, 400 Seventh Street, SW., Room 6206, Washington, DC 20590, telephone: (202) 366-1537.

Issued on: February 28, 1996.

William A. Boehly,

*Chairperson, Motor Vehicle Safety Research Advisory Committee.*

[FR Doc. 96-5086 Filed 3-4-96; 8:45 am]

BILLING CODE 4910-59-P

### Research and Development Programs Meeting Agenda

**AGENCY:** National Highway Traffic Safety Administration, DOT.

**ACTION:** Notice.

**SUMMARY:** This notice provides the agenda for a public meeting at which the National Highway Traffic Safety Administration (NHTSA) will describe and discuss specific research and development projects.

**DATES AND TIMES:** As previously announced, NHTSA will hold a public meeting devoted primarily to presentations of specific research and development projects on March 12, 1996, beginning at 1:30 p.m. and ending at approximately 5:00 p.m.

**ADDRESSES:** The meeting will be held at the Royce Hotel—Detroit Metro Airport, 31500 Wick Road, Romulus, MI 48174.

**SUPPLEMENTARY INFORMATION:** This notice provides the agenda for the twelfth in a series of public meetings to provide detailed information about NHTSA's research and development programs. This meeting will be held on March 12, 1996. The meeting was announced on February 12, 1996 (61 FR 5438). For additional information about the meeting consult that announcement.

Starting at 1:30 p.m. and concluding by 5:00 p.m., NHTSA's Office of Research and Development will discuss the following topics:

- Crash test dummy component development including agency plans and status regarding refinements to the Hybrid III dummy,
- Preliminary rearend collision avoidance system guidelines and pedestrian detection devices for school bus safety,

- Status and update on agency efforts for upgraded side impact protection,

- Status and plans for 1996 for the National Accident Sampling System Crashworthiness Data System (NASS CDS), and

- Online tracking system for NHTSA research projects—status and update of efforts to present information on NHTSA's ongoing research to the public.

NHTSA has based its decisions about the agenda, in part, on the suggestions it received by February 22, 1996, in response to the announcement published February 12, 1996.

As announced on February 12, 1996, in the time remaining at the conclusion of the presentations, NHTSA will provide answers to questions on its research and development programs, where those questions have been submitted in writing by 4:15 p.m. on March 4, 1995, to William A. Boehly, Associate Administrator for Research and Development, NRD-01, National Highway Traffic Safety Administration, Washington, DC 20590. Fax number: 202-366-5930.

**FOR FURTHER INFORMATION CONTACT:** Rita I. Gibbons, Staff Assistant, Office of Research and Development, 400 Seventh Street, SW, Washington, DC 20590. Telephone: 202-366-4862. Fax number: 202-366-5930.

Issued: February 28, 1996.

William A. Boehly,

*Associate Administrator for Research and Development.*

[FR Doc. 96-5087 Filed 3-4-96; 8:45 am]

BILLING CODE 4910-59-P

## Research and Special Programs Administration

[Notice No. 96-4]

### Information Collection Activities; Comment Request

**AGENCY:** Research and Special Programs Administration (RSPA), DOT.

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, the Research and Special Programs Administration invites comments on certain information collections, pertaining to hazardous materials transportation safety and oil spill prevention and response planning, for which RSPA intends to request approval from the Office of Management and Budget.



**DATES:** Interested persons are invited to submit comments on or before May 6, 1996.

**ADDRESSES:** Please address written comments to Dockets Unit (DHM-30), Room 8421, Research and Special Programs Administration, U.S. Department of Transportation, Washington, DC 20590-0001 (202) 366-5046. Comments may also be faxed to (202) 366-3753. Comments should identify this notice number (96-4) and the appropriate Office of Management and Budget (OMB) Control Number(s). Persons wishing to receive confirmation of receipt of their comments should include a self-addressed stamped postcard showing the notice number. Public information may be reviewed between the hours of 8:30 a.m. and 5:00 p.m., Monday through Friday, except holidays.

Requests for a copy of an information collection should be directed to Jackie Smith, Office of Hazardous Materials Standards (DHM-10), Research and Special Programs Administration, Room 8102, 400 Seventh Street, SW, Washington, DC 20590-0001, Telephone (202) 366-8553.

**FOR FURTHER INFORMATION CONTACT:** Jackie Smith, Office of Hazardous Materials Standards (DHM-10), Research and Special Programs Administration, Room 8102, 400 Seventh Street, SW, Washington, DC 20590-0001, Telephone (202) 366-8553.

**SUPPLEMENTARY INFORMATION:** Office of Management and Budget (OMB) regulations (5 CFR 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104-13) require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). This notice identifies information collections that RSPA is submitting to OMB for extension or reinstatement, as appropriate. These collections are contained in (1) 49 CFR 107, Hazardous Materials Program Procedures; (2) 49 CFR 110, Hazardous Materials Public Sector Training and Planning Grants; (3) 49 CFR 130, Oil Spill Prevention and Response Plans; and (4) 49 CFR 171 through 180, Hazardous Materials Regulations (HMR). RSPA has revised burden estimates, where appropriate, to reflect current reporting levels or adjustments based on changes in proposed or final rules published since the information collections were last approved. RSPA will request a three-year term of approval for each information collection activity and, when approved by OMB,

publish notice of the approval in the Federal Register.

Comments are invited on: (1) The need for the collection of information for the proper performance of the functions of the agency; (2) the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the information collection burden on respondents, such as use of automated, electronic or other technological means of collecting information. A summary of public comments will accompany RSPA's submission of the information collection requests to OMB.

The following information is provided for each information collection: (1) Title of the information collection, including former title if a change is being made; (2) OMB control number; (3) summary of the information collection activity, including the need for and use of the collection; (4) description of the affected public; (5) estimate of total annual reporting and recordkeeping burden; and (7) frequency of collection.

**Title:** Inspection and Testing of Portable Tanks and Intermediate Bulk Containers [Former title: Portable Tank Inspection and Testing].

**OMB Control Number:** 2137-0018.

**Summary:** This information collection consolidates provisions for documenting qualifications, inspections and tests pertaining to the manufacture and use of portable tanks and intermediate bulk containers under various provisions in parts 173, 178 and 180 of the HMR. It is needed to ascertain whether portable tanks and intermediate bulk containers have been qualified, inspected and retested in accordance with the HMR. For example, 49 CFR 173.32 requires that portable tanks be periodically retested, and prescribes both retest markings and retention of records as a demonstration of compliance. The information is used to verify that portable tanks and intermediate bulk containers meet required performance standards prior to being authorized for initial use or reuse as bulk packagings for hazardous materials.

**Affected Public:** Manufacturers and owners of portable tanks and intermediate bulk containers.

**Annual Reporting and Recordkeeping Burden:**

**Number of Respondents:** 314.

**Total Annual Responses:** 51,220.

**Total Annual Burden Hours:** 51,340.

**Frequency of Collection:** Design qualification testing is performed at the start of production for each new or different design type, periodic design type retesting is performed at one year intervals for intermediate bulk containers only, and periodic requalification of tanks in use is performed every 2-5 years, depending on the type of testing required and the tank specification. Certification markings are applied to each packaging at time of manufacture.

**Title:** Testing, Inspection, and Marking Requirements for Cylinders [Former title: Recordkeeping and Information Collection for Cylinders].

**OMB Control Number:** 2137-0022.

**Summary:** This information collection consolidates provisions for documenting qualifications, inspections and tests pertaining to the manufacture and use of cylinders under various provisions in parts 173, 178 and 180 of the HMR. It is needed to ascertain whether cylinders have been qualified, inspected and retested in accordance with the HMR. For example, provisions in 49 CFR 173.34 for qualification, maintenance and use of cylinders require that cylinders be periodically inspected and retested to ensure continuing compliance with packaging standards. Information collection requirements also address registration of retesters and marking of cylinders by retesters and recertifiers. The information is used to verify that cylinders meet required manufacturing standards prior to being authorized for initial use, and that once manufactured the cylinders are maintained and used in compliance with applicable requirements of the HMR as packagings for hazardous materials.

**Affected Public:** Fillers, owners, users and retesters of reusable cylinders.

**Annual Reporting and Recordkeeping Burden:**

**Number of Respondents:** 139,352.

**Total Annual Responses:** 153,287.

**Total Annual Burden Hours:** 171,681.

**Frequency of Collection:** Reports are required for cylinders as they are manufactured and initially tested. Cylinders are required to be marked after manufacture with specific information. Inspection reports are also required to verify compliance with the provisions of the HMR, including verification that the cylinders passed the required tests. Registration of retesters is performed on a one-time basis. Retester marking on a cylinder is performed once every 5 to 20 years depending on cylinder specification and type of service. Pressure verification for acetylene cylinders is performed daily.

*Title:* Hazardous Materials Incident Reports

*OMB Control Number:* 2137-0039

*Summary:* This collection is applicable upon occurrence of incidents as prescribed in 49 CFR 171.15 and 171.16. Basically, a Hazardous Materials Incident Report, DOT Form F 5800.1, must be completed by a carrier of hazardous materials after a hazardous material transportation incident occurs, such as a release of material, serious accident, evacuation or highway shutdown. Serious incidents meeting criteria in 49 CFR 171.15 also require a telephonic report by the carrier. This information collection enhances RSPA's ability to evaluate the effectiveness of its regulatory program, determine the need for regulatory changes and address emerging hazardous materials transportation safety issues. The requirement applies to all carriers engaged in the transportation of hazardous materials by rail, air, water and highway.

*Affected Public:* Each carrier who transports hazardous materials.

*Annual Reporting and Recordkeeping Burden:*

*Number of Respondents:* 700.

*Total Annual Responses:* 16,600.

*Total Annual Burden Hours:* 24,190.

*Frequency of Collection:* Reports are required upon occurrence of a reportable incident.

*Title:* Flammable Cryogenic Liquids [Previous title: Cryogenic Liquids Requirements].

*OMB Control Number:* 2137-0542.

*Summary:* Provisions in 49 CFR 177.818 require the carriage on a motor vehicle of written procedures for venting flammable cryogenic liquids and for responding to emergencies. Sections 173.318(g), 177.840(h), and 180.405(h) specify certain safety procedures and documentation requirements for drivers of these motor vehicles. These requirements are intended to ensure a high level of safety when transporting flammable cryogenics due to their extreme flammability.

*Affected Public:* Carriers of flammable cryogenic liquids in bulk.

*Annual Reporting and Recordkeeping Burden:*

*Number of Respondents:* 65.

*Total Annual Responses:* 18,200.

*Total Annual Burden Hours:* 1,213.

*Frequency:* A response is required for each shipment of a flammable cryogenic material.

*Title:* Approvals for Hazardous Materials.

*OMB Control Number:* 2137-0557.

*Summary:* There are over one hundred approval provisions contained

in the HMR and associated procedural regulations. Responses to these collections of information are required to obtain benefits, such as to become an approval or certification agency or obtain a variance from packaging or handling requirements based on information provided by the respondent. This information is used by RSPA to: (1) Determine whether applicants who apply to become designated approval agencies are qualified to evaluate package design, test packages, classify hazardous materials, etc.; (2) verify that various containers and special loading requirements meet the requirements of the HMR; (3) assure that regulated hazardous materials pose no danger to life and property during transportation; and (4) allow minor variations to regulatory requirements, based on information provided by respondents, without requiring the respondent to apply using less timely and more burdensome exemption procedures.

*Affected Public:* Businesses and other entities who must meet the approval requirements in the HMR.

*Annual Reporting and Recordkeeping Burden:*

*Number of Respondents:* 3,503.

*Total Annual Responses:* 3,853.

*Total Annual Burden Hours:* 18,302.

*Frequency:* On occasion of application for a benefit.

*Title:* Testing Requirements for Packaging.

*OMB Control Number:* 2137-0572.

*Summary:* Detailed packaging manufacturing specifications have been replaced by a series of performance tests that a non-bulk packaging must be capable of passing before it is authorized to be used for transporting hazardous materials. The HMR require proof that packagings meet these testing requirements. Manufacturers must retain records of design qualification tests and periodic retests. Manufacturers must notify, in writing, persons to whom packagings are transferred of any specification requirements that have not been met at the time of transfer. Subsequent distributors, as well as manufacturers must provide written notification. Performance-oriented packaging standards allow manufacturers and shippers much greater flexibility in selecting more economical packagings.

*Affected Public:* Each non-bulk packaging manufacturer that tests packaging to ensure the safe transportation of hazardous materials.

*Annual Reporting and Recordkeeping Burden:*

*Number of Respondents:* 5,000.

*Total Annual Responses:* 15,000.

*Total Annual Burden Hours:* 30,000.

*Frequency:* Tests are performed at start of production of a packaging design type and repeated at one or two-year intervals, depending on the type of packaging. Written notification is provided at time of first transfer, to each person to whom a packaging is transferred.

*Title:* Container Certification Statement [Previous title: Statement of Structural Serviceability for Freight Containers to be used for Class 1.1 and 1.2 Explosives].

*OMB Control Number:* 2137-0582.

*Summary:* As required in § 176.27, shippers of hazardous materials, in freight containers or transport vehicles by vessel, are required to certify that the freight container or transport vehicle is serviceable, that the hazardous materials are properly marked, labeled, or placarded, loaded and secured. For explosives in Division 1.1 and 1.2, shippers are required to certify on shipping documentation that the freight container or transport vehicle meets minimal structural serviceability requirements (see § 176.172). These requirements are intended to ensure an adequate level of safety for transport of hazardous materials aboard vessel and ensure consistency with similar requirements in international standards.

*Affected Public:* Shippers of hazardous materials, including explosives in freight containers or transport vehicles by vessel.

*Annual Reporting and Recordkeeping Burden:*

*Number of Respondents:* 530.

*Total Annual Responses:* 604,000.

*Total Annual Burden Hours:* 15,100.

*Frequency:* The statement is required for each shipment of hazardous material in a freight container or transport vehicle aboard a vessel.

*Title:* Hazardous Materials Public Sector Planning and Training Grants.

*OMB Control Number:* 2137-0586.

*Summary:* Part 110 of 49 CFR sets forth procedures for reimbursable grants for public sector planning and training in support of the emergency planning and training efforts of States, Indian tribes and local communities to deal with hazardous materials emergencies, particularly those involving transportation. Sections in this part address information collection and recordkeeping with regard to applying for grants, monitoring expenditures, reporting and requesting modifications.

*Affected Public:* State and local governments, Indian tribes.

*Annual Reporting and Recordkeeping Burden:*

*Number of Respondents:* 66.

*Total Annual Responses:* 66.

*Total Annual Burden Hours:* 4,082.

*Frequency:* Application for a grant is at the discretion of the applicant and can be made as frequently as every annual grant cycle. Financial status reports are submitted quarterly. Grantees must complete a performance report at the end of the grant period.

*Title:* Response Plans for Shipments of Oil [Previous title: Preparation of Response Plans for Shipments of Oil].

*OMB Control Number:* 2137-0591.

*Summary:* In recent years several major oil discharges damaged the marine environment of the United States. As required by the Federal Water Pollution Control Act, as amended by the Oil Pollution Act of 1990, RSPA has issued regulations that require preparation of written spill response plans and, in certain instances, submission of these plans to RSPA for the transportation of oil in bulk by motor vehicle or rail car. These plans are intended to aid in the mitigation of the effects of unintended discharges of oil to the environment.

*Affected Public:* Carriers that transport oil in bulk, by motor vehicle or rail.

*Annual Reporting and Recordkeeping Burden:*

*Number of Respondents:* 8,000.

*Total Annual Responses:* 8,000.

*Total Annual Burden Hours:* 10,560.

*Frequency:* One time report, plus notification of changes when needed.

Issued in Washington, DC, on February 28, 1996.

Edward T. Mazzullo,

*Director, Office of Hazardous Materials Standards.*

[FR Doc. 96-5064 Filed 3-4-96; 8:45 am]

**BILLING CODE 4910-60-P**

## **Surface Transportation Board<sup>1</sup>**

**[Finance Docket No. 32769]**

### **Central New England Railroad, Inc., Modified Certificate**

On October 11, 1995, Central New England Railroad, Inc. filed a notice under 49 CFR Part 1150, Subpart C—*Modified Certificate of Public Convenience and Necessity* to operate approximately 13.5-miles of an abandoned<sup>2</sup> rail line between milepost

<sup>1</sup> The ICC Termination Act of 1995, Pub. L. No. 104-88, 109 Stat. 803 (the Act), which was enacted on December 29, 1995, and took effect on January 1, 1996, abolished the Interstate Commerce Commission (ICC) and transferred certain functions and proceedings to the Surface Transportation Board (Board). Section 204(b)(1) of the Act provides, in general, that proceedings pending before the ICC on the effective date of that legislation shall be decided under the law in effect prior to January 1, 1996, insofar as they involve functions retained by the Act. This notice relates to a proceeding that was pending with the ICC prior to January 1, 1996, and to functions that are subject to Board jurisdiction pursuant to 49 U.S.C. 10901. Therefore, this notice applies the law in effect prior to the Act, and citations are to the former sections of the statute, unless otherwise indicated.

<sup>2</sup> The 5.5-mile portion of the line between milepost 12.5 (Hazardville, CT) and milepost 18.0 (East Windsor, CT), was formerly owned by the Trustee of Penn Central Transportation Company, one of the eastern railroads reorganized under the Regional Rail Reorganization Act, and was never

8.8 at Enfield, CT (on the Connecticut-Massachusetts State line) and milepost 23.3 at East Windsor Hill, CT, owned by the Connecticut Department of Transportation (ConnDOT).

The Commission will serve a copy of this notice on the Association of American Railroads (Car Service Division), as agent of all railroads subscribing to the car-service and car-hire agreement, and on the American Short Line Railroad Association.

Decided: February 28, 1996.

By the Commission, David M. Konschnick, Director, Office of Proceedings.

Vernon A. Williams,

*Secretary.*

[FR Doc. 96-5063 Filed 3-4-96; 8:45 am]

**BILLING CODE 4915-00-P**

designated in the United States Railway Associations's *Final System Plan* for transfer to Consolidated Rail Corporation (CR). The line was abandoned by the Trustee in 1976 pursuant to section 308 of the Regional Rail Reorganization Act of 1973, 45 U.S.C. 744(b) and acquired by the State of Connecticut's Department of Transportation (ConnDOT) for continued rail service.

The 3.7-mile portion of the line between milepost 12.5 (Hazardville, CT) and milepost 8.8 (Enfield, CT) was abandoned by the Boston and Maine Corporation in 1993. *See Boston and Maine Corporation—Abandonment Exemption—In Hartford County, CT, and Hampden County, MA, AB-32 (Sub-No. 62X), and Springfield Terminal Railway Company—Discontinuance Exemption—In Hartford County, CT, and Hampden County, AB-355 (Sub-No. 14X) (ICC served Nov. 24, 1993).*

The 4.3-mile portion of the line between milepost 18.0 and milepost 22.3 (East Windsor Hill, CT/CR milepost 6.77—Troy Road Connection) was abandoned by CR in 1987. *See Conrail Abandonment in Hartford County, CT, Docket No. AB-167 (Sub-No. 984N) (ICC served Feb. 23, 1987).* ConnDOT subsequently acquired this portion of the line on May 11, 1995, for continued rail service.

Executive Order

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Tuesday  
March 5, 1996

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**Part II**

**Department of  
Housing and Urban  
Development**

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24 CFR Part 941, et al.

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**Streamlining the Comprehensive  
Improvement Assistance and  
Comprehensive Grant Programs; Final  
Rule**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

### Office of the Assistant Secretary for Public and Indian Housing

#### 24 CFR Parts 941, 950, 965, and 968

[Docket No. FR-3967-F-01]

RIN 2577-AB59

### Streamlining the Comprehensive Improvement Assistance Program and Comprehensive Grant Program

**AGENCY:** Office of the Assistant Secretary for Public and Indian Housing, HUD.

**ACTION:** Final rule.

**SUMMARY:** This rule amends 24 CFR parts 950 (formerly 905) and 968 to streamline, simplify and eliminate unnecessary requirements for the Department's two modernization programs used in the public housing and Indian housing programs. The Comprehensive Improvement Assistance Program (CIAP) is used by Public Housing Agencies (PHAs) and Indian Housing Authorities (IHAs) that own or operate fewer than 250 public housing units. The Comprehensive Grant Program (CGP) is used by PHAs and IHAs that own or operate 250 or more public housing units.

The rule also combines into provisions of a part dealing with general provisions applicable to PHA-owned projects (part 965) the nearly identical provisions concerning prevailing wage rates that have been found in the development and modernization parts for public housing (parts 941 and 968).

**EFFECTIVE DATE:** April 4, 1996.

#### FOR FURTHER INFORMATION CONTACT:

For Public Housing: William J. Flood, Director, Office of Capital Improvements, Public and Indian Housing, Department of Housing and Urban Development, Room 4134, 451 Seventh Street, S.W., Washington, D.C. 20410-5000, telephone (202) 708-1640.

For Indian Housing: Deborah M. LaLancette, Director, Housing Management Division, Office of Native American Programs, Public and Indian Housing, Room B-133, Department of Housing and Urban Development, 451 Seventh Street S.W., Washington, D.C. 20410, telephone (202) 755-0088.

Hearing- or speech-impaired persons may use the Telecommunications Devices for the Deaf (TDD) by contacting the Federal Information Relay Service on 1-800-877-TDDY (1-800-877-8339) or (202) 708-9300. (Other than the "800" TDD number, telephone numbers are not toll-free.)

#### SUPPLEMENTARY INFORMATION:

##### I. Paperwork Burden

The information collection requirements contained in this rule remain essentially unchanged. They are merely moved to different section numbers as part of this consolidation effort. (See §§ 950.618, 950.622, 950.630, 950.632, 950.634, 950.636, 968.135, 968.145, 968.210, 968.215, 968.225, and 968.230, previously approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act (44 U.S.C. 3501-3520) under OMB control number 2577-0044 (CIAP). See also §§ 950.650, 950.656, 950.658, 968.310, 968.325, and 968.330, previously approved by OMB under control number 2577-0157 (CGP).)

##### II. Background

Upon assuming the leadership of the Department of Housing and Urban Development (HUD) in 1993, Secretary Cisneros made the reinvention of HUD one of his first priorities. HUD's reinvention efforts took place in the context of a broader, government-wide reinvention process, the National Performance Review, under the leadership of Vice President Gore. At that time, HUD established five program goals to accomplish its mission that involved working for healthy growth in cities, providing adequate housing for all, and protection of society's most vulnerable people.

HUD determined that one of the first steps needed in its transformation from the old HUD to a new HUD was the consolidation and streamlining of funding programs. HUD recently submitted to Congress sweeping changes to transform public housing to a resident-based program.

Another aspect of the reinvention involves HUD's rules, which have been at the forefront of HUD's reinvention efforts since those efforts commenced in 1993. The foundation of HUD's regulatory process is Executive Order 12866 (Regulatory Planning and Review) issued by President Clinton on September 30, 1993. This order directs agencies to, among other things, explore regulatory alternatives and, if regulations are determined to be necessary, to select approaches that maximize benefits and involve enhanced public accessibility and participation in the rulemaking process.

HUD has done a comprehensive review of 24 CFR part 968, Public Housing Modernization. Part 968 contains 3 subparts, covering general requirements and separate requirements for the Comprehensive Improvement

Assistance Program (CIAP) and Comprehensive Grant Program (CGP). Based on its comprehensive review, HUD has determined that certain provisions from CIAP and CGP can be consolidated in the general provisions, subpart A. HUD also has determined that there are a number of revisions that should be made to simplify subpart B for CIAP and subpart C for CGP. Similar changes are also being made to 24 CFR part 950, subpart I, which covers the modernization program requirements for Indian Housing.

In addition to the simplifications mentioned above and described in more detail in Part III below, the Department is also responding in this rule to public comments received on the interim CIAP rule published March 15, 1993 (58 FR 13916). This rule also makes changes resulting from experience gained during the Federal Fiscal Years (FFYs) 1993, 1994, and 1995 funding competitions (see Part IV below).

[The reader should note that, hereafter, for ease of discussion, the preamble to this final rule uses the term "housing authorities (HAs)" to refer to both public housing agencies (PHAs) and Indian Housing Authorities (IHAs) and the term "public housing" to refer to both Public and Indian housing, unless otherwise stated. In addition, the term "development" is used to refer to "low-income projects," as defined at section 3(b)(1) of the Act.]

##### III. Reinvention Changes for CIAP and CGP

As a part of other pending rulemakings, various Federal requirements that are applicable to a number of the Department's programs, including modernization, are being moved to Department-wide common rules. One example of such provisions are those now contained in § 968.110, Other Federal requirements.

The current section covers civil rights compliance, minority and women's business enterprise opportunity, lead-based paint poisoning prevention, environmental clearance, flood insurance, and wage rates, as well as audits, uniform administrative requirements, and energy conservation. Most of the civil rights authorities, including references to minority and women's business enterprise opportunity, have been consolidated into the Department-wide rule (24 CFR part 5) listing provisions applicable to all of the Department's programs. That rulemaking revised § 968.110 to refer to the Department-wide rule, leaving a few additional authorities in § 968.110(a). Another pending rulemaking addresses

the applicability of lead-based paint poisoning prevention.

This rulemaking also revises § 968.110 as follows: § 968.110(i), Audits, is being moved to a new § 968.145, Fiscal closeout; § 968.110(j), Uniform administrative requirements, is being moved to a new § 968.135, Contracting requirements; § 968.110(l), Energy conservation, is being moved to a revised § 968.115, Modernization and energy conservation standards; and the cross-reference in paragraph (e)(3) for preemption of prevailing wage rates is changed to 24 CFR 965.101. (Section 965.101 is amended in this rulemaking to broaden the coverage of its preemption of prevailing wage rates to extend to development and modernization, as well as to operations.)

Existing § 968.120, dealing with preemption of State prevailing wage requirements, is being moved to and combined with § 965.101.

The Indian housing program is not affected by the consolidation of general provisions by the other pending rulemaking. Consequently, § 950.120 still contains comparable provisions.

#### IV. Relation of Current Regulations Sections to Final Rule Sections

The following chart shows the locations of similar provisions:

New section	Current sections
950.604 .....	950.601
950.606 .....	950.667
950.608 .....	950.615, 950.666
950.610 .....	950.603
950.612 .....	[New provision]
950.614 .....	950.635
950.616 .....	950.639
950.618 .....	950.642
950.620 .....	950.645
950.622 .....	950.657
950.630 .....	950.618
950.632 .....	950.624
950.634 .....	950.648
950.636 .....	950.651
950.638 .....	[New provision]
950.640 .....	950.654, 950.675
950.650 .....	950.669
950.652 .....	950.672
950.654 .....	950.675
950.656 .....	950.678
950.658 .....	950.684
950.660 .....	950.687
968.104 .....	968.312
968.112 .....	968.210, 968.310
968.125 .....	968.225
968.130 .....	968.230
968.135 .....	968.235
968.140 .....	968.240
968.145 .....	968.260
968.210 .....	968.215
968.215 .....	968.220
968.225 .....	968.245
968.230 .....	968.250
968.235 .....	[New provision]
968.240 .....	968.345
968.310 .....	968.315

New section	Current sections
968.315 .....	968.320
968.320 .....	968.325
968.325 .....	968.330
968.330 .....	968.340
968.335 .....	968.345

#### V. Public Comments and Description of the Simplified CIAP

##### A. Public Comments

The Department received public comments on the March 1993 interim rule from four HAs and two HA interest groups (National Association of Housing and Redevelopment Officials (NAHRO) and Public Housing Authorities Directors Association (PHADA)). The commenters agreed that HUD has made substantial progress in simplifying the CIAP, and pointed out additional areas for simplification or clarification.

**Relocation requirements.** The March 1993 interim rule revised parts 905 (now 950) and 968 by updating the displacement, relocation and acquisition requirements pursuant to the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, as amended, and by removing the relocation requirements from the "Other program requirements" sections and creating separate sections for the relocation requirements at new §§ 905.117 (now 950.117) and 968.108.

**Comment:** PHADA and two HAs recommended that HUD be required to respond to an HA's request for a determination of coverage under the relocation requirements (§§ 968.108(g)(3) and 950.117(g)(3)) within 30 calendar days or within a longer stated period or provide a rebuttal period or the HA's interpretation would be accepted as final.

**Response:** The Department agrees that dialogue between HUD and an HA is important and should start in the planning stage. Technical assistance on relocation matters is readily available from Community Planning and Development relocation staff in HUD Field Offices. HUD will make every effort to respond promptly to HA requests for assistance. However, HUD cannot restrict the time period for a response as suggested. HUD's relocation rules implementing statutory requirements guaranteeing benefits to eligible persons cannot be amended by this rulemaking. In fact, HUD relies on regulations issued by the Department of Transportation for government-wide requirements, at 49 CFR part 24 (see 24 CFR part 42). A delay in HUD's response does not relieve an HA of its responsibility to comply with the

Uniform Relocation Act, where applicable.

**Definition of modernization capability.** **Comment:** PHADA commented that the determination of no modernization capability be afforded an appeal to the Regional Administrator, and that HUD be required to inform the HA as to why the determination was made and what facts the determination is based on. **Response:** With regard to the Public Housing Management Assessment Program (PHMAP), the PHA may appeal its score on the Modernization indicator to the Field Office; if that appeal is denied, the PHA may appeal to HUD Headquarters. The HUD reorganization eliminated the Regional Offices. With regard to the CIAP technical review factor of modernization capability, HUD will provide guidance in the revised CIAP Handbook on how Field Offices should score the technical review factors, including modernization capability, to ensure greater uniformity among Field Offices. In addition, HUD has made clarifying changes to the definitions of modernization capability at §§ 950.102 and 968.205 to ensure that no arbitrary exclusion of participation due to lack of modernization capability will occur.

**Management improvement costs.** **Comment:** PHADA agreed with HUD on allowing CIAP programs composed solely of management improvements. Two HAs questioned whether training related to management improvements is eligible. **Response:** Training costs related to carrying out CIAP-approved physical and management improvements are eligible. See §§ 950.608(g)(2)(ii) and 968.112(g)(2)(ii). **Comment:** Two HAs also asked if office space and storage space are eligible costs. **Response:** Such costs are eligible. See §§ 950.608(c) and 968.112(c).

**Comment:** PHADA indicated that some Field Offices have traditionally frowned on management improvement requests. **Response:** This rule clarifies that eligible management improvements, either development specific or HA-wide, may be approved as single work items under Other Modernization. In addition, this rule specifically states that the establishment of a preventive maintenance system or improvement of an existing system is an eligible management improvement. See §§ 950.608(g)(2)(v) and 968.112(g)(2)(v).

**Reasonable cost and total development cost (TDC).** **Comment:** PHADA agreed with the definition of reasonable cost (hard costs not exceeding 90% of TDC) for most cases, but suggested exceptions for compliance with accessibility requirements and

remediating environmental problems, such as asbestos and lead-based paint. It was suggested that these types of situations are not taken into account by the cost indices upon which TDC is based and, therefore, should be excluded from the definition. In addition, many IHAs with large numbers of homeownership (Mutual Help) units are performing comprehensive-type, not piecemeal, modernization.

*Response:* The rule has been revised to use the previous definition of reasonable cost (90% of TDC) and to handle any special cases on a case-by-case basis. The Department had tried a method that allowed more flexibility, which we have now determined to be inappropriate.

In the August 30, 1995, final rule streamlining the CGP, the Department added a second method of determining cost reasonableness to provide HAs with greater flexibility in determining the cost of rehabilitation versus the cost of demolition and new development. HAs could choose one of two methods which were: (1) unfunded modernization hard costs do not exceed 90 percent of computed total development cost (TDC); or (2) individual work items are reasonable in accordance with National cost indices, adjusted by local conditions and the HA's own recent procurement experience. During the FY 1995 program year, it became evident that use of the second method was having unintended consequences by allowing some very high cost developments to be determined to have reasonable cost. This result is inappropriate in the current environment of limited funding. Since it is clear that resources for Public and Indian Housing will remain constrained, it is incumbent on both the Department and the HAs to assure maximum return for the dollars invested. It is not tolerable to allow large-scale Federal investments to be made in properties which will remain uneconomical or provide marginally suitable housing even after such investments are made.

Accordingly, the Department has eliminated the second method of determining cost reasonableness, but has provided that the 90 percent of TDC limit may be exceeded where justified, and applied this procedure to both CIAP and CGP. If the HA and the Field Office recommend funding for a development which exceeds 90 percent of TDC, the Field Office must submit written justification to Headquarters for final decision.

*Social services.* *Comment:* PHADA and three HAs suggested that eligible costs include the direct provision of

social services, because it is essential to enhance the living conditions and self-sufficiency opportunities for residents of small HAs. It was suggested that HUD allow start-up costs and reasonable operating costs for three years conditioned on the HA being able to provide HUD up-front with a reasonable plan for continuing the program after the CIAP funds are expended. *Response:* Although the 1995 Rescissions Act expanded the eligible activities that may be funded under Section 14 of the Act with FFY 1995 and prior year modernization funds, to include the direct provision of social services, there is no permanent statutory authority for eligibility of such activities. Therefore, the rule excludes the direct provision of social services from future year funding unless otherwise provided by law. If a later appropriation act specifically permits eligibility for these services, that change will be handled by language in the Notices of Funding Availability for the affected years.

*Program benefit.* *Comment:* PHADA and four HAs questioned the program benefit rules at §§ 950.615(j)(3) and 968.210(j)(3) (now found in §§ 950.608(n)(3) and 968.112(n)(3)). *Response:* The rule provides that where the physical or management improvement will benefit programs other than Public or Indian housing, such as Section 8 or local revitalization, eligible costs are limited to the amount directly attributable to the Public or Indian Housing Program. CIAP assistance must be used for the purposes expressed in the statute and not for other programs or purposes. OMB Circular A-87 also requires this program benefit rule. There is no statutory authority to use CIAP funds to subsidize the Section 8 program as suggested.

*Ineligible costs.* *Comment:* PHADA and four HAs mentioned arguments HAs have had with Field Offices regarding ineligible costs. The rule at §§ 950.615(k) and 968.210(k) stated that an HA shall not make luxury improvements, or carry out any other ineligible activities, as specified by HUD. *Response:* HUD has consulted with HA industry groups on the eligibility and ineligibility of various work items. In January 1994, the Department revised its policy, under the Public Housing Development Program and the CGP, on work items previously considered amenities to provide HAs with maximum flexibility. The Department is now extending that revised policy to the CIAP to allow work items that are modest in design and cost, but still promote the blending in of Public and Indian housing with the design and architecture of the

surrounding community by including amenities, quality materials and design and landscaping features that are customary for the locality and culture. However, no additional operating subsidy will be provided. Accordingly, the CIAP provisions on ineligible costs at §§ 950.615(b) and 968.210(b) have been revised and moved to §§ 950.608(o) and 968.112(o) to incorporate this policy. The CGP provisions on ineligible costs at §§ 950.666(c) and 968.310(c) also have been revised and moved to §§ 950.608 and 968.112 to incorporate this policy, consolidating in one section for IHAs and another for PHAs the policy applicable to both the CIAP and CGP.

*Administrative and maintenance space guidelines.* *Comment:* PHADA and three HAs commented that HUD needs to reexamine the standards for allowable administrative and maintenance space. *Response:* HUD has consulted with HA industry groups on this issue during the CGP rulemaking. A survey by NAHRO concluded that the variation among HAs is so great in terms of the programs which they operate for the benefit of the Public or Indian Housing Program, it is impossible to establish standards for such space. The Department agrees that establishing space standards is very difficult and, accordingly, is eliminating the maximum space guidelines for management, maintenance and community space. Instead, Field Offices are given, at §§ 950.608(c) and 968.112(c), the authority to approve space in accordance with the general principles of program need and benefit, as well as sound business practices.

*Expedited NOFA publication.* *Comment:* PHADA and two HAs urged HUD to publish CIAP NOFAs within 60 days of passage of an Appropriations Act or 30 calendar days from the start of a FFY, whichever is later, assuming there are no major statutory changes adopted in the Appropriations Act. *Response:* Secretary Cisneros has made expedited publication of NOFAs a priority. However, the amount of funds available for the CIAP each year cannot be determined until the modernization formula is run. The formula determines the funding split between the CIAP and the CGP. Revisions to the CGP (e.g., earlier update of the Formula Characteristics Report for CGP agencies) have enabled the Department to run the modernization formula earlier in the FFY, which, in turn, has benefitted the CIAP. The Department will continue its efforts to make CIAP funds available as soon as possible in the FFY.

*Application process.* *Comment:* PHADA suggested that a general format

should be developed by HUD to assist small HAs gather the information being requested. *Response:* The CIAP Application form (HUD-52822) provides a format for HAs to record their physical and management improvement needs. The Department believes that any other format may be burdensome to small HAs. The Department is open to the development of guidance material which may be helpful to small HAs and welcomes specific suggestions.

*Replacement estimate for equipment, systems or structural elements.*

*Comment:* PHADA and two HAs questioned why the CIAP Application required identification of a cost estimate for the equipment, systems or structural elements which would normally be replaced over the remaining period of the Annual Contributions Contract (ACC) or during the 30-year period beginning on the date of submission of the application. *Response:* This was a burdensome statutory requirement from which HUD sought legislative relief. A technical amendment to section 14(d)(2) of the Act, was signed into law on April 11, 1994 (Pub. L. 103-233, 108 Stat. 369). Accordingly, the Department has eliminated this requirement on Form HUD-52822, CIAP Application.

*Application requirements for management improvements.* *Comment:* PHADA requested simplification of the application requirements for management improvements. *Response:* It appeared to PHADA that the regulation at §§ 950.610(g)(2)(i) and 968.215(c)(2) required a general recital of the management and administrative capabilities of the HA. In order to clarify that such items were only examples of eligible management improvements, the items have been moved to the eligible costs section at §§ 950.608(g)(2)(i) and 968.112(g)(2)(i).

*Development deficiencies.* *Comment:* PHADA pointed out a possible problem with §§ 950.618(e)(1)(ii) and 968.215(e)(1)(ii). Each development for which work is proposed must be at least three years old from the end of the initial operating period (EIOP). Since warranties are generally one year and some builders may go bankrupt, PHADA asked for relief to be provided for the unusual circumstance in which early assistance from CIAP is required. Such relief would be simpler than having to come to the Assistant Secretary for Public and Indian Housing for a regulatory waiver. *Response:* In order to make the CIAP consistent with the CGP, the Department has changed the threshold for development eligibility from EIOP to Date of Full Availability (DOFA) and under ACC at

§§ 968.210(e)(1) and 950.630(e)(1). However, the Department stresses that the first avenue of correction of a development deficiency is from the architect or contractor, as appropriate. Where there is no approved actual development cost certificate (ADCC), HUD will continue to look to development funds first to correct the development deficiency; if development funds are not available, the Field Office may approve use of CIAP funds for correction, without Headquarters approval. Once there is an approved ADCC, any subsequently identified development deficiency may be funded by CIAP funds.

*Eligibility review.* *Comment:* PHADA was concerned about a situation where an HA is improperly managed and may be found to be ineligible under the regulatory criteria even if a new executive director or key staff member has been employed and is sincerely trying to correct the HA's problems. PHADA thought this situation may require a waiver of the eligibility criteria at §§ 950.618(e) or 968.215(e). *Response:* HUD disagrees with that interpretation and refers the commenter to the revised definitions of modernization and management capability found in §§ 968.205 and 950.102. A Troubled PHA shall be considered for funding of non-emergency improvements where it is making reasonable progress toward meeting the performance targets established in its memorandum of agreement (or equivalent) or has obtained alternative oversight of its management functions. The Field Office shall determine whether the HA has a reasonable prospect of acquiring management or modernization capability through CIAP-funded management improvements and administrative support, such as hiring staff or contracting for assistance.

*Technical review factors.* *Comment:* PHADA and two HAs questioned if the technical review factors are relevant for CIAP, considering the size of the HAs participating in CIAP. Specifically, items 5, 6, and 7 which deal with resident involvement, initiatives, and employment are difficult for many small HAs. While PHADA was not opposed to these items in theory, it was concerned about their practicality. PHADA suggested reexamination of these technical review factors since small HAs find it is very difficult to get residents involved and the opportunities for resident employment with the HA are severely limited. NAHRO stated that the degree to which resident programs are operating is more often a function of fund availability and the type of unit, elderly or family. Also, in some small

towns, the local elected leadership may be anti-public housing. Item 8 (local government support for proposed modernization) may prevent improvements needed by the residents. NAHRO urged that while vacancies are a problem which should be addressed whenever possible through CIAP, when assigning weights to this factor, the Department should utilize data from the Vacancy Reduction Program to ascertain the extent to which modernization needs are causing vacancies in this size category of HAs. NAHRO indicated that anecdotal evidence thus far indicates that the vacancies in this size group are often caused by market conditions or an insufficient number of applicants, not modernization need.

*Response:* Section 14(d) of the Act requires CIAP Applications to be developed in consultation with the appropriate local officials and with residents of the housing developments for which assistance is requested; therefore, the technical review factors must, at a minimum, reflect these requirements. The other factors are a matter of Secretarial discretion. The Department supports strong resident involvement in all aspects of the Public or Indian Housing Program. These technical review factors reflect HUD's goals for the CIAP. HUD realizes that resident involvement varies depending on the size and resources of the HA, and those distinctions are considered in scoring the technical review factors. It also should be noted that the technical review factor on extent of vacancies has been clarified to indicate that points will be given only if the vacancies are not due to insufficient demand.

*PHMAP and rating.* *Comment:* PHADA and one HA were concerned about reinventing CIAP and PHMAP. It was suggested that no PHA should be rated down in management capability unless there is a failing PHMAP score or some unusual change occurs at the PHA. Conversely, a low PHMAP score should be used to increase the chances of needed management improvements being funded. *Response:* If a PHA needs CIAP funds for a management improvement to address a low PHMAP score, it is not penalized. Again, refer to the revised definition of management capability in § 968.205.

*Application review.* *Comment:* PHADA suggested that an application should be rejected only on new grounds once. PHADA wanted to avoid possible endless resubmissions. *Response:* The Department notes that the completeness review is not complex and that operating experience has indicated that only a relatively small number of HAs are required to correct or resubmit



documents. HUD cannot overlook deficiencies in HA submissions. Although HUD will make every effort to provide technical assistance to HAs before the application deadline date, HAs have a responsibility to prepare applications which meet HUD requirements.

*Debriefing for unsuccessful applications.* *Comment:* PHADA and two HAs were concerned that too often an HA not receiving the CIAP assistance it requested is not adequately informed as to why it was not funded. PHADA requested that the regulation be modified to require a debriefing for HAs whose applications are not funded so they can improve their situation for the next funding round. *Response:* HUD already requires the Field Office to inform an HA in writing as to why its application was unsuccessful. This requirement has been included in the final rule at §§ 950.630(i) and (j) and 968.210(i) and (j).

*Residual receipts.* *Comment:* PHADA and NAHRO noted that an HA will not be selected for Joint Review if it has residual receipts to carry out the modernization activities for which it is applying. PHADA, NAHRO and one HA indicated that residual receipts should be used as long as a HA is allowed to retain 50 percent of the maximum allowable reserves or \$50,000, whichever is higher. This way, a reasonable amount of reserves can be used and at the same time the HA is not placed in financial jeopardy. *Response:* The Department has eliminated the requirement for PHAs to remit residual receipts, effective for HAs with fiscal years beginning on or after January 1, 1995. This change will make the retention or return of residual receipts a moot issue since there will no longer be funds identified as residual receipts and no provision on residual receipts in the rule. Accordingly, the Department has eliminated the provision in § 968.210(i) regarding non-selection for Joint Review where the PHA has residual receipts.

*Contracting and budget revisions approvals.* *Comment:* PHADA, NAHRO and one HA disagreed with HUD's approval procedures for contracting and budget revisions. They suggested that these situations could be modified so that if HUD does not act on an HA's submission within 15 calendar days, it is automatically approved and the project can proceed. NAHRO requested that HUD clarify the processes to be used by Field Offices in establishing more frequent reporting or more stringent requirements related to thresholds or prior HUD approval. NAHRO urged that PHMAP should be used and cross referenced here.

*Response:* Field Offices are required to establish thresholds as high as possible to give CIAP agencies flexibility while protecting HUD's interests in the contracting area. These thresholds are based on an HA's in-house technical capability and past performance. The revised CIAP Handbook will establish time frames for Field Office review and action on documents which must be submitted for prior HUD approval. The Department will continue to urge Field Offices to respond in a timely manner, including use of form letters, where appropriate, and to monitor Field Office performance in this area.

The Department has streamlined the requirements regarding budget revisions by requiring that a budget revision be submitted for prior HUD approval only where an HA plans to deviate from the competitively funded modernization program. Prior HUD approval is not required for revisions that are consistent with, and necessary to, completion of the original modernization program. The regulation also clarifies that modernization funds may not be used for developments that are not covered by the original CIAP application, even where there are leftover funds remaining after the originally approved modernization program has been completed. See §§ 968.225 and 950.634.

*Modernization coordinator or contract administrator.* *Comment:* PHADA seeks appeal rights whenever HUD requires an HA to hire a modernization coordinator or contract administrator in order to receive the CIAP grant. PHADA considers this to be justified in certain cases, but urges that the regulation specifically allow the HA to appeal this to the Regional Administrator and also be informed specifically why HUD feels this is necessary. PHADA suggest that if these modifications are not made, this provision could be abused by some due to petty personal differences. NAHRO suggested that the Department establish in PHMAP the requirements or conditions for HAs who have performed poorly in the past. Additionally, NAHRO suggested that if the Field Office requires a contract administrator, the HA must be notified at Joint Review. This practice would give the HA the opportunity to protest, or if there is agreement, the time to search for one who can take over immediately following the execution of the ACC.

*Response:* It has been the Department's experience that some smaller HAs do not have in-house capacity to administer the CIAP and require administrative and technical assistance to implement their approved programs. The Department must be assured that approved programs will be

carried out in an economical and effective manner. During Joint Review, the Field Office will discuss with the HA the type and amount of administrative and technical assistance which it may need during implementation of its CIAP program. However, such needs may not be finalized until the scope of work and amount of funding are determined after Joint Review. The Field Office has the final determination on this matter.

*Force account.* *Comment:* PHADA and two HAs recommended that §§ 950.635(a) and 968.225(a) be changed to allow HAs to use force account labor to carry out modernization in all cases except where it is specifically forbidden. *Response:* To provide a reward for high-performing HAs and to achieve consistency with the CGP, the Department has eliminated prior HUD approval for use of force account labor by PHAs that are designated as both over-all high performers and mod-high performers under the PHMAP and by all IHAs. See §§ 950.612(a) and 968.120(a). PHAs that are not both over-all high performers and mod-high performers will continue to obtain prior HUD approval to use force account labor through their CIAP budgets or budget revision submissions. The Field Office will approve or disapprove such use as part of the budget/budget revision approval process.

*Modernization priorities.* *Comment:* Following the CGP model, PHADA urged HUD to respect an HA's priorities and only modify the priorities after the HA agrees to the modification. *Response:* The key difference between CIAP and CGP is that CIAP is a competitive, not a formula, program. Although HUD does not set priorities for HAs in either program, HUD must assess the relative extent and urgency of need among CIAP agencies in rating and ranking the CIAP Applications.

*Comparability with CGP.* *Comment:* NAHRO noted that the CIAP is now similar in many respects to the CGP. It encouraged HUD to strive for comparability between the two programs on the issue of technical review. *Response:* Except for statutory differences, the Department has made every attempt to make the CIAP comparable to the CGP.

*Formula approach.* *Comment:* PHADA and one HA requested HUD to examine whether the competitive CIAP process could be replaced by a CGP formula distribution. *Response:* As part of HUD's reinvention, the Department has proposed to the Congress the establishment of a Capital Fund in the first stage of transforming public and Indian housing. The Capital Fund

would replace both the existing CIAP and CGP programs and provide formula funding to all HAs, regardless of size. In FFY 1995, the 904 CGP agencies were eligible to receive 89 percent of the available funds and the 2,496 CIAP agencies were eligible to receive 11 percent of the available funds.

**Board Resolution.** *Comment:* NAHRO questioned the HUD requirement for the Board of Commissioners to certify that the budget, implementation schedule or other documents are accurate and complete. It was suggested that the Board should be able to delegate responsibility to the Executive Director to make certain certifications on behalf of the HA. Accountability could be achieved by the fact that the Executive Director is accountable to the Board.

**Response:** HUD requires that, after an HA is selected for funding, the HA submit the Board Resolution Approving the CIAP Budget, Form HUD-52820, with the CIAP budget and other required documents. The Board resolution does not require certification as to the accuracy and completeness of the budget, including the implementation schedule, and other documents. The Board resolution does contain various certifications and agreements regarding HA compliance with HUD policies, procedures, requirements, regulations and Federal statutes. The Department is willing to accept the certification by the Executive Director, in lieu of the Board, in these matters, where the Executive Director has been delegated this authority by the Board and is permitted to do so under State law.

#### *B. Description of Simplified CIAP*

This final rule continues the simplification of the CIAP, as set forth in the interim rule, in the areas of HA application requirements, modernization types, application processing and implementation. The final rule provides increased efficiency, reduces unnecessary requirements, and provides new flexibility for both the participating HAs and HUD. The changes to CIAP are the same for both Public and Indian housing, with the exception of the Mutual Help Program. Many of these changes are the result of recent meaningful dialogue with small HAs and experience gained through administering CIAP.

#### *C. Simplification of Procedures for Obtaining Approval of a Modernization Program*

Previously, the process for receiving CIAP funds involved multiple steps. This final rule continues the approach set forth in the interim rule regarding

the elimination, combination or simplification of many of those previous requirements.

HUD expects that after modernization funds for a particular Federal Fiscal Year become available, HUD would continue to publish in the Federal Register a NOFA and the time frame for submission for applications. HUD currently publishes an annual CIAP NOFA for this purpose and, in the last two years, the CIAP NOFA has been significantly improved to describe clearly submission requirements, available amounts, eligibility, technical review factors, application processing, Joint Review selections, and funding decisions. The improvements to the CIAP NOFA also are intended to promote fair competition in the program.

This final rule establishes the following steps for obtaining approval of a modernization program: (1) application submission by the HA; (2) completeness review by HUD; (3) eligibility review by HUD; (4) technical review, including rating and ranking, by HUD; and (5) Joint Review by HUD and the HA; (6) funding decisions by HUD; (7) budget submission by HA; and (8) ACC amendment. Based on actual operating experience in FFYs 1993, 1994, and 1995, processing time was significantly reduced.

The first step for obtaining a CIAP grant is the application submission by the HA. As previously noted, the requirement to provide a cost estimate for the replacement of equipment, systems or structural elements over a 30-year period is no longer mandated by the statute and has been eliminated.

An HA has the option of including only the specific developments for which it is requesting funding or of including all its developments in the CIAP Application. The consequences of not including all its developments in the CIAP Application are that HUD may not, as a result of Joint Review, consider funding of any non-emergency work at excluded developments or subsequently approve use of leftover funds at excluded developments. The benefits derived from including all its developments are the ability to: (1) revise specific work items among developments at Joint Review; and (2) use leftover funds upon completion of the modernization for modernization needs at other developments covered by the application. An HA must evaluate and describe its modernization needs and the estimated costs for each development covered by the application.

HUD will ensure that documentation and other information regarding each

application submitted pursuant to the CIAP NOFA are sufficient to indicate the basis upon which assistance was provided or denied. This material, including any letters of support, will be made available for public inspection for a five-year period beginning not less than 30 calendar days after the award of the assistance. Material will be made available in accordance with the Freedom of Information Act (5 U.S.C. 552) and HUD's implementing regulation at 24 CFR part 15. In addition, HUD will include the recipients of assistance pursuant to the CIAP NOFA in its quarterly Federal Register notice of all recipients of HUD assistance awarded on a competitive basis. (See 24 CFR §§ 12.14(a) and 12.16(b), and the notice published in the Federal Register on January 16, 1992 (57 FR 1942), for further information on these requirements.)

The second step for obtaining a CIAP grant is the completeness review by HUD. The final rule clarifies that if the CIAP Application (Form HUD-52822) or any other essential document, as specified in the NOFA, is missing, the HA's application will be considered substantially incomplete and, therefore, ineligible for further processing. If there is a technical mistake, such as no signature on a submitted form, the HA will be given an opportunity to correct the deficiency. This is not additional time to substantially revise the application. Deficiencies that may be corrected at this time are inadvertently omitted documents, as specified in the NOFA, or clarifications of previously submitted material and other changes which are not of such a nature as to improve the competitive position of the application. In addition, the final rule clarifies that if the HA does not correct the deficiency within the specified time period, the HA is ineligible for further processing.

The third step for obtaining a CIAP grant is the eligibility review by HUD. Based on operating experience in FFYs 1993, 1994, and 1995, the Department has made the following changes from the interim rule:

- (1) Eliminated work item eligibility and need which may be difficult to determine before Joint Review;
- (2) Changed the requirement that each development on which work is proposed be at least three years old from the End of Initial Operating Period (EIOP) to a requirement that each development must have reached the Date of Full Availability (DOFA) and be under ACC. Also, clarified the eligibility of a development/building/unit assisted with Major Reconstruction of Obsolete Projects (MROP) funding, under section

5(j)(2) of the Act (see Section F of this Preamble). These changes make development eligibility under the CIAP consistent with the CGP;

(3) Eliminated the restriction on processing where the HA has not submitted the fiscal audit to HUD within one year after the end of the audit period, or requested an extension for submission, in conformance with the Single Audit Act requirements. The Department has decided to use regular monitoring as a more effective method of obtaining audit compliance rather than eliminating the HA up-front from full funding consideration;

(4) Eliminated the restriction on processing where the HA owes funds to the Department as a result of excess development, modernization or operating funds previously provided and the HA has not repaid the funds, or has not entered into a repayment agreement, or is not meeting its obligations under a repayment agreement. The Department has decided to use regular monitoring as a more effective method of obtaining funds owed to the Department rather than eliminating the HA up-front from full funding consideration;

(5) Where the HA has not completed the structural changes identified by the Section 504 Needs Assessment, added the restriction on processing to Emergency Modernization or physical work needed to meet Section 504 requirements;

(6) Where the HA has not complied with the statutory requirement to complete Lead Based Paint (LBP) testing on all pre-1978 family units, added the restriction on processing to Emergency Modernization or work needed to complete LBP testing; and

(7) Where the HA has not complied with Fair Housing and Equal Opportunity (FHEO) requirements, continued the restriction on processing to Emergency Modernization or work needed to remedy civil rights deficiencies.

The fourth step for obtaining a CIAP grant is technical review by HUD. The Department is retaining the provisions of the interim rule regarding technical processing, categorizing the eligible HAs and their developments into two processing groups (Group 1 for Emergency Modernization and Group 2 for Other Modernization), and rating and ranking of applications in Group 2. Preference is given to all HA applications in Group 1 since such applications involve emergencies which are an immediate threat to resident health or safety. Accordingly, such applications are not rated and ranked

during technical processing and are automatically selected for Joint Review.

The Field Office rates the Group 2 HAs/developments against the technical review factors to determine relative ranking. In accordance with section 14(h) of the Act, the Department will continue the preference given to HAs which request assistance for developments having conditions which threaten the health or safety of the residents or having a significant number of vacant, substandard units, and which have demonstrated a capability of carrying out the proposed activities. This preference is reflected in the technical review factors and their maximum point scores.

The final rule recognizes the change in the Department's field structure by eliminating reference to the Regional Office. Since each Field Office receives its own allocation of CIAP funds, the Field Office will proceed to Joint Review selection after rating and ranking. The Field Office will identify for selection the highest ranking HA applications in Group 2 in descending order, and other Group 2 HAs with lower ranking applications but with high priority needs which most reasonably approximate the amount of modernization which can be funded by the Field Office. High priority needs are non-emergency needs, but related to: health or safety; vacant, substandard units; structural or system integrity; or compliance with statutory, regulatory or court-ordered deadlines. Again, all Group 1 applications will be automatically selected for Joint Review.

The fifth step for obtaining a CIAP grant is Joint Review. The purpose of Joint Review is for the Field Office to discuss with an HA the proposed modernization program, as set forth in the application, and determine the size of the grant, if any, to be awarded. The Field Office will notify those HAs whose applications have been selected for further processing as to whether the Joint Review will be conducted on-site or off-site (e.g., by telephone or in-office meeting). If conducted on-site, the Joint Review may include an inspection of the proposed physical work. An HA will prepare for Joint Review by preparing a draft CIAP budget and reviewing the other items to be covered during Joint Review, as prescribed by HUD. The Field Office will review long-term viability and reasonable cost determinations during Joint Review.

HAs not selected for Joint Review will be notified by letter stating the reasons, such as the low priority of its physical improvement needs relative to available funding. If, prior to scheduling the Joint Reviews, there is determined to be a

duplication of funding, the HA will not be selected for Joint Review. Where a duplication of funding is determined during Joint Review, the HA will not be selected for funding.

The sixth and seventh steps for obtaining a CIAP grant are funding decisions by HUD and budget submission by the HA. Upon completion of Joint Review, the Field Office will adjust the HAs/developments and work items to be funded and the amounts to be awarded, including processing groups, as necessary, based on information obtained at Joint Review, the results of FHEO review, and completion of the environmental reviews. After Congressional notification, the Field Office will announce the HAs selected for CIAP grants, subject to their submission of an approvable CIAP budget and other required documents. The Field Office will request the funded HA to submit a CIAP budget, which includes an implementation schedule, a resolution by the HA Board of Commissioners containing certifications required by HUD, and any other required documents. The Field Office will select all bona fide emergencies in Group 1 for funding before funding Group 2 applications. HAs not selected for funding will be notified in writing of the reason for non-selection.

After Field Office approval of the CIAP budget, the eighth step for obtaining a CIAP grant is that the Field Office and the HA enter into an ACC Amendment in order for the HA to obtain modernization funds. The ACC Amendment will require low-income use of the housing for not less than 20 years from the date of the ACC Amendment (subject to sale of homeownership units in accordance with the terms of the ACC). It should be noted that HUD has the authority to condition the ACC Amendment (e.g., to require an HA to hire a modernization coordinator or contract administrator to administer its modernization program).

The final rule continues the streamlined ACC Amendment process by allowing Field Office program staff to complete and forward the ACC Amendment to the HA with the budget approval letter, and by allowing the HA Executive Director, where authorized by the Board and permitted by State law, to sign and return the ACC Amendment to the Field Office for execution. This is identical to the ACC Amendment process in the CGP. Excluding Mutual Help developments, an HA also will, where necessary, execute and file for record a Declaration of Trust, as provided under the ACC, to protect the rights and interests of HUD throughout

the 20-year period during which the HA is obligated to operate the developments receiving modernization funds in accordance with the ACC, the Act, and HUD regulations and requirements.

#### *D. Other Simplifications and Revisions to CIAP*

When the revised CGP final rule was published on August 30, 1994, at 59 FR 44810, the Department eliminated the requirement that the cost of non-emergency health and safety work items increase the purchase price and amortization period for Turnkey III or Mutual Help homebuyer families. This requirement already was eliminated for the CGP and CIAP at §§ 950.602 and 968.102.

CIAP agencies shall administer previously approved CIAP grants under this final rule. It would be problematic for both HUD and CIAP agencies to administer CIAP programs in progress under differing requirements. HUD will continue to allow revisions to previously approved CIAP budgets, where appropriate.

#### *E. Major Reconstruction of Obsolete Projects (MROP)*

Section 111(b) of the Housing and Community Development Act of 1992 amended section 14(c) of the Act and provided that a building which is assisted with MROP funding (under section 5(j)(2) of the Act) is not eligible for CIAP funding. This statutory provision was implemented in the interim rule at § 968.101(b)(5). To provide further clarification, § 968.101(b)(5) is revised in the final rule to clarify that a development/building/unit is eligible for CIAP funding where it was funded under MROP after FFY 1988 and has reached DOFA or where it was funded under MROP during FFYs 1986–1988 and all MROP funds have been expended.

#### *F. Long-Term Viability*

The final rule clarifies at §§ 905.608(b) and 968.112(b) that HAs may expend funds on a non-viable development for essential non-routine maintenance needed to keep the property habitable until the demolition or disposition application is approved and residents are relocated.

#### *G. Previous Participation*

On June 20, 1994, the Department published at 59 FR 31521, an interim rule, which eliminated the requirement for HAs to submit Form HUD–2530, Previous Participation Certificate, on modernization contracts. Accordingly, §§ 950.642(d)(3) and 968.235(d)(3), requiring previous participation

clearance, have been eliminated and §§ 950.642(g) (now 950.618) and 968.235 (now 968.135) have been modified to delete reference to previous participation.

#### *H. Time Extensions*

The Department has added new §§ 950.638 and 968.235 to specify requirements regarding time extensions to the obligation or expenditure deadline date approved by HUD in the original implementation schedule. HUD approves implementation schedules as part of the budget approval process (refer to Part III of the CIAP budget). The Department is allowing CIAP agencies to execute (as CGP agencies now are authorized to do), without prior HUD approval, time extensions commensurate with the delay no later than 30 calendar days after the obligation or expenditure deadline date where the HA is able to certify that the delay is due to reasons outside of the HA's control, such as the need to use leftover funds from a completed modernization program for additional work, unforeseen delays in contracting or contract administration, litigation, and HUD or other institutional delay. Where the delay is not due to reasons outside of the HA's control, the HA must request HUD approval of a time extension no later than 30 calendar days after the obligation or expenditure deadline date to avoid recapture of funds.

#### *I. Threshold for Performance and Payment Bond for CGP Agencies*

The Department's procurement regulations, as set forth in 24 CFR 85.36(h), require that HA contractors furnish a bid guarantee and a performance bond and payment bond for each construction or equipment contract over \$100,000. For the CIAP and the CGP, the Department had reduced that threshold from \$100,000 to \$25,000 in order to protect the Federal interest. The Department has reconsidered this matter and has raised the threshold from \$25,000 to \$100,000 for both CIAP and CGP agencies at §§ 950.618(b) and 968.135(b). The Department inadvertently omitted the requirement of the bid guarantee when it reduced the threshold for the performance and payment bonds and has included it with this rule. In addition, the Department is continuing its policy of allowing for both CGP and CIAP agencies two other alternative methods of assurance to performance and payment bonds, which are a twenty percent cash escrow or a twenty-five percent letter of credit.

## VI. Findings and Certifications

### *Environmental Impact*

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50 which implement section 102(2)(C) of the National Environmental Policy Act of 1969, 42 U.S.C. 4332. The Finding of No Significant Impact is available for public inspection and copying during regular business hours (7:30 a.m. to 5:00 p.m. weekdays) in the Office of the Rules Docket Clerk, Room 10272, 451 Seventh Street, SW., Washington, DC 20410.

### *Federalism Impact*

The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, *Federalism*, has determined that the rule does not have substantial, direct effects on HAs. The revised modernization program is consistent with federalism principles since it reduces unnecessary burdens on HAs. While the program is revised, the primary change is only in the way that HUD processes and reviews HA modernization activities, and not the modernization activities themselves. This rule will not diminish the importance of State and local governments with respect to the Federal Government. As a result, the rule is not subject to review under the order.

### *Impact on the Family*

This rule has been developed in accordance with Executive Order 12606, *the Family*. The General Counsel, as the Designated Official under the Executive Order, has determined that this rule does not have the potential for significant impact on family formation, maintenance, or general well-being, since its effect is limited to revising program procedures for HAs applying for discretionary grants. Families are not affected since HAs will continue to carry out modernization activities at public housing developments.

### *Regulatory Flexibility Act*

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)) has reviewed and approved this rule, and in so doing certifies that this rule will not have a significant economic impact on a substantial number of small entities. The rule codifies revisions to the existing CIAP under which HAs receive modernization assistance from HUD on a competitive basis. HUD does not anticipate a significant economic impact on small entities since HAs will continue to carry out their modernization activities by entering

into contracts for the work as they now do.

#### Catalog of Domestic Assistance

The Catalog of Domestic Assistance numbers for the programs affected by this rule are 14.146, 14.147, 14.850, 14.851, 14.852, and 15.141.

#### List of Subjects

##### 24 CFR Part 941

Grant programs—housing and community development, Loan programs—housing and community development, Public housing.

##### 24 CFR Part 950

Aged, Grant programs—housing and community development, Grant programs—Indians, Indians, Individuals with disabilities, Low and moderate income housing, Public housing, Reporting and recordkeeping requirements.

##### 24 CFR Part 965

Energy conservation, Government procurement, Grant programs—housing and community development, Lead poisoning, Loan programs—housing and community development, Public housing, Reporting and recordkeeping requirements, Utilities.

##### 24 CFR Part 968

Grant programs—housing and community development, Indians, Loan programs—housing and community development, Public housing, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, parts 941, 950, 965, and 968 of title 24 of the Code of Federal Regulations are amended as follows:

#### PART 941—PUBLIC HOUSING DEVELOPMENT

1. The authority citation for 24 CFR part 941 continues to read as follows:

Authority: 42 U.S.C. 1437b, 1437c, 1437g, and 3535(d).

2. In § 941.208, paragraph (c) is revised to read as follows:

##### § 941.208 Other Federal requirements.

\* \* \* \* \*

(c) *Prevailing wage rates.* See part 965 of this chapter for applicable requirements on this subject.

\* \* \* \* \*

3. In § 941.503, paragraph (d) is revised to read as follows:

##### § 941.503 Construction requirements.

\* \* \* \* \*

(d) *Prevailing wage rates.* See § 965.101 of this chapter.

#### PART 950—INDIAN HOUSING PROGRAMS

4. The authority citation for 24 CFR part 950 continues to read as follows:

Authority: 25 U.S.C. 450e(b); 42 U.S.C. 1437aa–1437ee, and 3535(d).

5–6. Section 950.102 is amended by adding a definition of “*other modernization (modernization other than emergency)*” in alphabetical order, and by revising the definitions of “*emergency modernization*”, “*modernization capability*”, and “*modernization project*”, to read as follows:

##### § 950.102 Definitions.

\* \* \* \* \*

*Emergency modernization (CIAP).* A type of modernization program for a development that is limited to physical work items of an emergency nature, that pose an immediate threat to the health or safety of residents or is related to fire safety, and that must be corrected within one year of CIAP funding approval.

\* \* \* \* \*

*Modernization capability.* An IHA has modernization capability if it is:

(1) Not designated as high risk under § 950.135; or

(2) Designated as high risk, but has a reasonable prospect of acquiring modernization capability through CIAP-funded management improvements and administrative support, such as hiring staff or contracting for assistance. An IHA that has been classified high risk with regard to modernization is eligible for emergency modernization only, unless it is making reasonable progress toward meeting the performance targets established in its management improvement plan under § 950.135(f)(2) or has obtained alternative oversight of its modernization functions. Where an IHA does not have a funded modernization program in progress, the Area ONAP shall determine whether the IHA has a reasonable prospect of acquiring modernization capability through hiring staff or contracting for assistance.

\* \* \* \* \*

*Modernization project.* The improvement of one or more existing Indian housing developments under an unique number designated for that modernization program (CIAP). For each modernization project, HUD and the IHA shall enter into an ACC amendment, requiring low-income use of the housing for not less than 20 years from the date of the ACC amendment (subject to sale of homeownership units

in accordance with the terms of the ACC).

\* \* \* \* \*

*Other Modernization (modernization other than emergency).* A type of modernization program for a development that includes one or more physical work items, where HUD determines that the physical improvements are necessary and sufficient to extend substantially the useful life of the development, and/or one or more development specific or IHA-wide management work items (including planning costs), and/or LBP testing, professional risk assessments, interim containment, and abatement.

\* \* \* \* \*

7. Subpart I of Part 950, is revised to read as follows:

#### Subpart I—Modernization Program

##### General Provisions

##### Sec.

- 950.600 Purpose and applicability.
- 950.602 Special requirements for Turnkey III and Mutual Help developments.
- 950.604 Allocation of funds under section 14.
- 950.606 Reserve for emergencies and disasters.
- 950.608 Eligible costs.
- 950.610 Modernization and energy conservation standards.
- 950.612 Force account.
- 950.614 Initiation of modernization activities.
- 950.616 Fund requisition.
- 950.618 Contracting requirements.
- 950.620 On-site inspections.
- 950.622 Fiscal closeout.

##### Comprehensive Improvement Assistance Program (For IHAs That Own or Operate Fewer Than 250 Indian Housing Units)

- 950.630 Procedures for obtaining approval of a modernization program.
- 950.632 Resident and homebuyer participation.
- 950.634 Budget revisions.
- 950.636 Progress reports.
- 950.638 Time extensions.
- 950.640 HUD review of IHA performance.

##### Comprehensive Grant Program (For IHAs That Own or Operate 250 or More Indian Housing Units)

- 950.650 Determination of formula amount.
- 950.652 Comprehensive plan (including Five-Year Action Plan).
- 950.654 HUD review and approval of comprehensive plan (including Five-Year Action Plan).
- 950.656 Annual submission of activities and expenditures.
- 950.658 IHA Performance and Evaluation Report.
- 950.660 HUD review of IHA performance.

**Subpart I—Modernization Program****General Provisions****§ 950.600 Purpose and applicability.**

(a) *Purpose.* The purpose of this subpart is to set forth the policies and procedures for the Modernization program, authorizing HUD to provide financial assistance to Indian Housing Authorities (IHAs).

(b) *Applicability.* (1) The sections under the undesignated heading "General Provisions" apply to all modernization under this subpart. The sections under the undesignated heading "Comprehensive Improvement Assistance Program" (CIAP) set forth the requirements and procedures for the CIAP for IHAs that own or operate fewer than 250 Indian housing units. An IHA that qualifies for participation in the Comprehensive Grant Program (CGP) is not eligible to participate in the CIAP. The sections under the undesignated heading "Comprehensive Grant program (CGP)" set forth the requirements and procedures for the CGP for IHAs that own or operate 250 or more Indian housing units. An IHA that has already qualified to participate in the CGP remains eligible to participate in the CGP so long as it owns or operates at least 200 units.

(2) This subpart applies to IHA-owned low-income Indian housing developments (including developments managed by a Resident Management Corporation pursuant to a contract with the IHA). This subpart also applies to the implementation of modernization programs which were approved before FFY 1996. Rental developments that are planned for conversion to homeownership under sections 5(h), 21, or 301 of the Act (42 U.S.C. 1437c, 1437s, 1437aaa), but that have not yet been sold by an IHA, continue to qualify for assistance under this subpart. This subpart does not apply to developments under the Section 23 Leased Housing Non-Bond Financed program, the Section 10(c) Leased program, or the Section 23 or Section 8 Housing Assistance Payments programs.

(c) *Transition.* Any amount that HUD has obligated to an IHA shall be used for the purposes for which the funding was provided, or:

(1) For a CGP IHA, for purposes consistent with an approved annual statement or five-year action plan submitted by the IHA, as the IHA determines to be appropriate; or

(2) For a CIAP IHA, in accordance with a revised CIAP budget under § 950.634.

(d) *Other applicable requirements.* See subpart A of this part for applicable

requirements, other than the Act, that apply to modernization under this subpart I.

(e) *Approved information collections.* The following sections of this subpart have been approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 and assigned OMB approval number 2577-0044: §§ 950.618, 950.622, 950.630, 950.632, 950.634, and 950.636. The following sections of this subpart have been similarly approved and assigned approval number 2577.0157: §§ 950.650, 950.656, and 950.658.

**§ 950.602 Special requirements for Turnkey III and Mutual Help developments.**

(a) *Modernization costs.*

Modernization work on a Mutual Help or Turnkey III unit shall not increase the purchase price or amortization period of the home.

(b) *Eligibility of paid-off and conveyed units for assistance.* (1) *Paid-off units.* A Mutual Help or Turnkey III unit that is paid off but has not been conveyed at the time work is included for it in the CIAP application or CGP Annual Statement is eligible for any physical improvements provided under § 950.608. However, in accordance with the provisions of § 950.440(e)(8), an IHA may perform nonemergency work on a paid-off Mutual Help unit only after all delinquencies are repaid.

(2) *Conveyed units.* Where modernization work has been approved prior to conveyance, the IHA may complete the work even if title to the unit is subsequently conveyed before the work is completed. However, once conveyed, the unit is not eligible for additional or future assistance. An IHA shall not use funds provided under this subpart for the purpose of modernizing units if the modernization work was not approved before conveyance of title.

(c) *Other.* The homebuyer family shall be in compliance with its financial obligations under its homebuyer agreement in order to be eligible for nonemergency physical improvements, with the exception of work necessary to meet statutory and regulatory requirements (e.g., accessibility for disabled persons, lead-based paint testing, interim containment, professional risk assessment, and abatement) and the correction of development deficiencies.

Notwithstanding the above requirement, an IHA may, with prior HUD approval, complete nonemergency physical improvements on any homeownership unit if the IHA demonstrates that, due to economies of scale or geographic constraints, substantial cost savings may

be realized by completing all necessary work in a development at one time.

**§ 950.604 Allocation of funds under section 14.**

(a) *General.* This section describes the process for allocating modernization funds to the aggregate of IHAs and PHAs participating in the CIAP (i.e., agencies that own or operate fewer than 250 units), and to individual IHAs and PHAs participating in the CGP (i.e., agencies that own or operate 250 or more units). The program requirements governing PHA participation in the CIAP and CGP are contained in 24 CFR part 968.

(b) *Set-aside for emergencies and disasters.* For each FFY, HUD shall reserve from amounts approved in the appropriation act for grants under this part and part 968 of this title, an amount not to exceed \$75 million (which shall include unused reserve amounts carried over from previous FFYs), which shall be made available to IHAs and PHAs for modernization needs resulting from natural and other disasters, and from emergencies. HUD shall replenish this reserve at the beginning of each FFY. Any unused funds from previous years may remain in the reserve until allocated. The requirements governing the reserve for disasters and emergencies and the procedures by which an IHA may request such funds are set forth in § 950.606.

(c) *Set-aside for credits for mod troubled PHAs under 24 CFR part 968, subpart C.* (1) *General.* After deducting amounts for the reserve for natural and other disasters and for emergencies under paragraph (b) of this section, HUD shall set aside no more than five percent of the remaining amount for the purpose of providing credits to PHAs under 24 CFR part 968, subpart C that were formerly designated as mod troubled agencies under the Public Housing Management Assessment Program (PHMAP) at 24 CFR part 901. The purpose of this set-aside is to compensate such PHAs for amounts previously withheld by HUD because of their prior designation as a mod troubled agency.

(2) *Nonapplicability to IHAs.* Since the PHMAP performance indicators under 24 CFR part 901 do not apply to IHAs, these agencies cannot be deemed mod troubled for purposes of the CGP. Hence, IHAs are not subject to any reduction in funding under section 14(k)(5)(a) of the Act, nor do they participate in the set-aside of credits established under paragraph (c)(1) of this section.

(d) *Formula allocation based on relative needs.* After determining the

amounts to be reserved under paragraphs (b) and (c) of this section, HUD shall allocate the amount remaining pursuant to the formula set forth in paragraphs (e) and (f) of this section, which are designed to measure the relative backlog and accrual needs of IHAs and PHAs.

(e) *Allocation for backlog needs.* HUD shall allocate half of the formula amount under paragraph (d) of this section based on the relative backlog needs of IHAs and PHAs, as follows:

(1) *Determination of backlog need.* (i) *Statistically reliable data.* Where HUD determines that the data concerning the categories of backlog need identified under paragraph (e)(4) of this section are statistically reliable for individual IHAs and PHAs with 250 or more units, or the aggregate of IHAs and PHAs with fewer than 250 units not participating in the formula funding portion of the modernization program, it will base its allocation on direct estimates of the statutory categories of backlog need, based on the most recently available, statistically reliable data.

(ii) *Statistically reliable data are unavailable.* Where HUD determines that statistically reliable data concerning the categories of backlog need identified under paragraph (e)(4) of this section are not available for individual IHAs and PHAs with 250 or more units, it will base its allocation of funds under this section on estimates of the categories of backlog need using:

(A) The most recently available data on the categories of backlog need under paragraph (e)(4) of this section;

(B) Objectively measurable data concerning the following IHA or PHA, community, and development characteristics:

(1) The average number of bedrooms in the units in a development (Weighted at 2858.7);

(2) The proportion of units in a development available for occupancy by very large families (Weighted at 7295.7);

(3) The extent to which units for families are in high-rise elevator developments (Weighted at 5555.8);

(4) The age of the developments, as determined by the DOFA date (date of full availability). In the case of acquired developments, HUD will use the DOFA date unless the IHA provides HUD with the actual date of construction, in which case HUD will use the age of the development (or for scattered sites, the average age of all the buildings), subject to a 50 year cap. (Weighted at 206.5);

(5) In the case of a large agency, the number of units with 2 or more bedrooms (Weighted at .433);

(6) The cost of rehabilitating property in the area (Weighted at 27544.3);

(7) For family developments, the extent of population decline in the unit of general local government determined on the basis of the 1970 and 1980 censuses (Weighted at 759.5); and

(C) An equation constant of 1412.9.

(2) *Calibration of backlog need for developments constructed prior to 1985.*

The estimated backlog need, as determined under either paragraphs (e)(1)(i) or (e)(1)(ii) of this section, shall be adjusted upward for developments constructed prior to 1985 by a constant ratio of 1.5 to more accurately reflect the costs of modernizing the categories of backlog need under paragraph (e)(4) of this section, for the Indian housing stock as of 1991.

(3) *Deduction for prior modernization.* HUD shall deduct from the estimated backlog need, as determined under either paragraphs (e)(1)(i) or (e)(1)(ii) of this section, amounts previously provided to an IHA or PHA for modernization, using one of the following methods:

(i) *Standard deduction for prior CIAP and MROP.* HUD shall deduct 60 percent of the CIAP funds made available on an IHA-wide or PHA-wide basis from FFY 1984 to 1991, and 40 percent of the funds made available on a development-specific basis for the Major Reconstruction of Obsolete Projects (MROP) (not to exceed the estimated formula need for the development), subject to a maximum 50 percent deduction of an IHA's or PHA's total need for backlog funding;

(ii) *Newly constructed units.* Units with a DOFA date of October 1, 1991 or thereafter will be considered to have a zero backlog; or

(iii) *Acquired developments.* Developments acquired by an IHA with major rehabilitation, with a DOFA date of October 1, 1991 or thereafter, will be considered to have a zero backlog.

(4) *Categories of backlog need.* The most recently available data to be used under either paragraphs (e)(1)(i) or (e)(1)(ii) of this section shall pertain to the following categories of backlog need:

(i) Backlog of needed repairs and replacements of existing physical systems in Indian housing developments;

(ii) Items that shall be added to developments to meet HUD's modernization standards under § 950.610, and State, local and tribal codes; and

(iii) Items that are necessary or highly desirable for the long-term viability of a development, in accordance with HUD's modernization standards.

(f) *Allocation for accrual needs.* HUD shall allocate the other half remaining under the formula allocation under

paragraph (d) of this section based upon the relative accrual needs of IHAs and PHAs, determined as follows:

(1) *Statistically reliable data.* If HUD determines that statistically reliable data are available concerning the categories of need identified under paragraph (f)(3) of this section for individual IHAs and PHAs with 250 or more units and for the aggregate of IHAs and PHAs with fewer than 250 units, it shall base its allocation of assistance under this section on the needs that are estimated to have accrued since the date of the last objective measurement of backlog needs under paragraph (e)(1)(i) of this section; or

(2) *Statistically reliable data are unavailable.* If HUD determines that statistically reliable data concerning the categories of need identified under paragraph (f)(3) of this section are not available for individual IHAs and PHAs with 250 or more units, it shall base its allocation of assistance under this section on estimates of accrued need using:

(i) The most recently available data on the categories of backlog need under paragraph (f)(3) of this section;

(ii) Objectively measurable data concerning the following IHA or PHA, community, and development characteristics:

(A) The average number of bedrooms in the units in a development (Weighted at 100.1);

(B) The proportion of units in a development available for occupancy by very large families (Weighted at 356.7);

(C) The age of the developments (Weighted at 10.4);

(D) The extent to which the buildings in developments of an agency average fewer than 5 units (Weighted at 87.1);

(E) The cost of rehabilitating property in the area (Weighted at 679.1);

(F) The total number of units of each IHA or PHA that owns or operates 250 or more units (Weighted at .0144); and

(iii) An equation constant of 602.1.

(3) *Categories of need.* The data to be provided under either paragraph (f)(1) or (f)(2) of this section shall pertain to the following categories of need:

(i) Backlog of needed repairs and replacements of existing physical systems in Indian housing developments; and

(ii) Items that shall be added to developments to meet HUD's modernization standards under § 950.610, and State, local, and tribal codes.

(g) *Allocation for CIAP.* The formula amount determined under paragraphs (e) and (f) of this section for IHAs and PHAs with fewer than 250 units shall be allocated to IHAs in accordance with



the requirements under the undesignated heading of this subpart "Comprehensive Improvement Assistance Program" (CIAP) and to PHAs in accordance with the requirements of 24 CFR part 968, subpart B.

(h) *Allocation for CGP.* The formula amount determined under paragraphs (e) and (f) of this section for IHAs with 250 or more units shall be allocated in accordance with the requirements under the undesignated heading of this subpart "Comprehensive Grant Program," and for PHAs in accordance with the requirements of 24 CFR part 968, subpart C. An IHA that is eligible to receive a grant under the CGP may appeal the amount of its formula allocation under this section in accordance with the requirements set forth in § 950.650. An IHA that is eligible to receive modernization funds under the CGP because it owns or operates 250 or more units, is disqualified from receiving assistance under the CIAP under this part.

(i) *Use of formula allocation.* Any amounts allocated to an IHA under paragraphs (e) and (f) of this section may be used for any eligible activity under this subpart, notwithstanding that the allocation amount is determined by allocating half based on the relative backlog needs and half based on the relative accrual needs of IHAs and PHAs.

(j) *Calculation of number of units.* For purposes of determining under this section the number of units owned or operated by an IHA or PHA, and the relative modernization needs of IHAs and PHAs, HUD shall count as one unit each existing rental, Mutual Help, and section 23 Bond-Financed unit under the ACC, except that it shall count as one-fourth of a unit each existing unit under the Turnkey III program. New development units that are added to an IHA's or PHA's inventory will be added to the overall unit count so long as they are under ACC amendment and have reached DOFA by the first day in the FFY in which the formula is being run. Any increase in units (reaching DOFA and under ACC amendment) as of the beginning of the FFY shall result in an adjustment upwards in the number of units under the formula. New units reaching DOFA after this date will be counted for formula purposes as of the following FFY.

(k) *Demolition, disposition, and conversion of units.* (1) *General.* Where an existing unit under an ACC is demolished, disposed of, or converted into a larger or smaller unit, HUD shall not adjust the amount the IHA or PHA receives under the formula, unless more

than one percent of the units are affected on a cumulative basis. Where more than one percent of the existing units are demolished, disposed of, or converted, HUD shall reduce the formula amount for the IHA or PHA over a 3-year period to reflect removal of the units from the ACC.

(2) *Determination of one percent cap.* In determining whether more than one percent of the units are affected on a cumulative basis, HUD will compare the units eligible for funding in the initial year under formula funding with the number of units eligible for funding for the current year under formula funding, and shall base its calculations on the following:

(i) Increases in the number of units resulting from the conversion of existing units will be added to the overall unit count so long as they are under ACC amendment by the first day in the FFY in which the formula is being run;

(ii) Units that are lost as a result of demolition, disposition, or conversion shall not be offset against units subsequently added to an IHA's or PHA's inventory;

(iii) For purposes of calculating the number of converted units, HUD shall regard the converted size of the unit as the appropriate unit count (e.g., a unit that originally was counted as one unit under paragraph (j) of this section, but which later was converted into two units, shall be counted as two units under the ACC).

(3) *Phased-in reduction of units.* (i) *Reduction less than one percent.* If HUD determines that the reduction in units under paragraph (k)(2) of this section is less than one percent, the IHA or PHA will be funded as though no change had occurred.

(ii) *Reduction greater than one percent.* If HUD determines that the reduction in units under paragraph (k)(2) of this section is greater than one percent, the number of units on which formula funding is based will be the number of units reported as eligible for funding for the current program, plus two-thirds of the difference between the initial year and the current year in the first year, plus one-third of the difference in the second year, and at the level of the current year in the third year.

(iii) *Exception.* A unit that is conveyed under the Mutual Help or Turnkey III programs will result in an automatic (rather than a phased-in) reduction in the unit count. Paid-off Mutual Help or Turnkey III units continue to be counted until they are conveyed.

(4) *Subsequent reductions in unit count.* (i) Once an IHA's or PHA's unit

count has been fully reduced under paragraph (k)(3)(ii) of this section to reflect the new number of units under the ACC, this new number of units will serve as the base for purposes of calculating whether there has been a one percent reduction in units on a cumulative basis.

(ii) A reduction in formula funding, based upon additional reductions to the number of an IHA's or PHA's units, will also be phased in over a 3-year period, as described in paragraph (k)(2) of this section.

#### **§ 950.606 Reserve for emergencies and disasters.**

(a) *Emergencies.* (1) *Eligibility for assistance.* An IHA (including an IHA that is determined to be high risk under § 950.135) may obtain funds at any time, for any eligible emergency work item as defined in § 950.102 (for IHAs participating in CGP) or for any eligible emergency work item (described as emergency modernization in § 950.102) (for IHAs participating in CIAP), from the reserve established under § 950.604(b). However, emergency reserve funds may not be provided to an IHA participating in CGP that has the necessary funds available from any other source, including its annual formula allocation under § 950.604(e) and (f), other unobligated modernization funds, and its replacement reserves under § 950.608. An IHA is not required to have an approved Comprehensive Plan under § 950.652 before it can request emergency assistance from this reserve. Emergency reserve funds may not be provided to an IHA participating in CIAP unless it does not have the necessary funds available from any other source, including unobligated CIAP, and no CIAP modernization funding is available from HUD for the remainder of the fiscal year.

(2) *Procedure.* To obtain emergency funds, an IHA shall submit a request, in a form to be prescribed by HUD, that demonstrates that without the requested funds from the set-aside under this section, the IHA does not have adequate funds available to correct the conditions that present an immediate threat to the health or safety of the residents. HUD will immediately process a request for such assistance, and if it determines that the IHA's request meets the requirements of paragraph (a)(1) of this section, it shall approve the request, subject to the availability of funds in the reserve.

(3) *Repayment.* A CGP IHA that receives assistance for its emergency needs from the reserve under § 950.604(b) shall repay such assistance from its future allocations of assistance,



as available. For IHAs participating in the CGP, HUD shall deduct up to 50 percent of an IHA's succeeding year's formula allocation under § 950.604(e) and (f) to repay emergency funds previously provided by HUD to the IHA. The remaining balance, if any, shall be deducted from an IHA's succeeding years' formula allocations.

(b) *Natural and other disasters.* (1) *Eligibility for assistance.* An IHA (including an IHA that has been determined by HUD not to be administratively capable under § 950.135) may request assistance at any time from the reserve under § 950.604(b) for the purpose of permitting the IHA to respond to a natural or other disaster. To qualify for assistance, the disaster shall pertain to an extraordinary event affecting only one or a few IHAs, such as an earthquake or hurricane. Any disaster declared by the President (or that HUD determines would qualify for a Presidential declaration if it were on a larger scale) qualifies for assistance under this paragraph. An IHA may receive funds from the reserve regardless of the availability of other modernization funds or reserves, but only to the extent its needs are in excess of its insurance coverage. An IHA is not required to have an approved Comprehensive Plan under § 950.652 before it can request assistance from the reserve under § 950.604(b).

(2) *Procedure.* To obtain funding for natural or other disasters under § 950.604(b), an IHA shall submit a request, in a form prescribed by HUD, that demonstrates that it meets the requirements of paragraph (b)(1) of this section. HUD will immediately process a request for such assistance, and if it determines that the request meets the requirements under paragraph (b)(1) of this section, it will approve the request, subject to the availability of funds in the reserve.

(3) *Repayment.* Funds provided to an IHA under paragraph (b)(1) of this section for natural and other disasters are not required to be repaid.

#### § 950.608 Eligible costs.

(a) *General.* An IHA may use financial assistance received under this part for the following eligible costs:

(1) For a CGP IHA, the eligible costs are:

(i) Undertaking activities described in its approved Annual Statement under § 950.656(e) and approved Five-Year Action Plan under § 950.652(e)(5);

(ii) Carrying out emergency work, whether or not the need is indicated in the IHA's approved Comprehensive Plan, including Five-Year Action Plan, or Annual Statement;

(iii) Funding a replacement reserve to carry out eligible activities in future years, subject to the restrictions set forth in paragraph (f) of this section;

(iv) Preparing the Comprehensive Plan and Five-Year Action Plan under § 950.652 and the Annual Submission under § 950.656, including reasonable costs necessary to assist residents to participate in a meaningful way in the planning, implementation and monitoring process; and

(v) Carrying out an audit, in accordance with 24 CFR part 44.

(2) For a CIAP IHA, the eligible costs are activities approved by HUD and included in an approved CIAP budget.

(b) *Demonstration of viability.* Except in the case of emergency work, an IHA shall only expend funds on a development for which the IHA has determined, and HUD agrees, that the completion of the improvements and replacements (for CGP IHAs, as identified in the comprehensive plan) will reasonably ensure the long-term physical and social viability of the development at a reasonable cost (as defined in § 950.102), or for essential non-routine maintenance needed to keep the property habitable until the demolition or disposition application is approved and residents are relocated.

(c) *Physical improvements.* Eligible costs include alterations, betterments, additions, replacements, and non-routine maintenance that are necessary to meet the modernization and energy conservation standards prescribed in § 950.610. These mandatory standards may be exceeded when the IHA (and HUD in the case of CIAP IHAs) determine that it is necessary or highly desirable for the long-term physical and social viability of the individual development. Development specific work includes work items that are modest in design and cost, but still blend in with the design and architecture of the surrounding community by including amenities, quality materials and design and landscaping features that are customary for the locality and culture. The Field Office has the authority to approve nondwelling space where such space is needed to administer, and is of direct benefit to, the Public and Indian Housing Program. If demolition or disposition is proposed, an IHA shall comply with subpart M of this part. Additional dwelling space may be added to existing units.

(d) *Turnkey III developments.* (1) *General.* Eligible physical improvement costs for existing Turnkey III developments are limited to work items that are not the responsibility of the homebuyer families and that are related

to health and safety, correction of development deficiencies, physical accessibility, energy audits and cost-effective energy conservation measures, or LBP testing, interim containment, professional risk assessment and abatement. In addition, management improvements are eligible costs.

(2) *Ineligible costs.* Routine maintenance or replacements, and items that are the responsibility of the homebuyer families are ineligible costs.

(3) *Exception for vacant or non-homebuyer-occupied Turnkey III units.* (i) Notwithstanding the requirements of paragraph (d)(1) of this section, an IHA may substantially rehabilitate a Turnkey III unit whenever the unit becomes vacant or is occupied by a non-homebuyer family in order to return the unit to the inventory or make the unit suitable for homeownership purposes. An IHA that intends to use funds under this paragraph must identify in its CIAP Application or CGP Annual Submission the estimated number of units proposed for substantial rehabilitation and subsequent sale. In addition, an IHA must demonstrate that it has homebuyers who both are eligible for homeownership, in accordance with the requirements of this part, and have demonstrated their intent to be placed into each of the Turnkey III units proposed to be substantially rehabilitated.

(ii) Before an IHA may be approved for substantial rehabilitation of a unit under this paragraph (d), it must first deplete any Earned Home Payments Account (EHPA) or Non-Routine Maintenance Reserve (NRMR) pertaining to the unit, and request the maximum amount of operating subsidy. Any increase in the value of a unit caused by its substantial rehabilitation under this paragraph shall be reflected solely by its subsequent appraised value, and not by an automatic increase in its selling price.

(e) *Demolition and conversion costs.* Eligible costs include:

(1) Demolition of dwelling units or non-dwelling facilities, where the demolition is approved by HUD under subpart M of this part, and related costs, such as clearing and grading the site after demolition and subsequent site improvement to benefit the remaining portion of the existing development; and

(2) Conversion of existing dwelling units to different bedroom sizes or to non-dwelling use.

(f) *Replacement reserve costs (for CGP only).* (1) Funding a replacement reserve to carry out eligible activities in future years is an eligible cost, subject to the following restrictions:

(i) Annual CGP funds are not needed for existing needs, as identified by the IHA in its needs assessments; or

(ii) A physical improvement requires more funds than the IHA would receive under its annual formula allocation; or

(iii) A management improvement requires more funds than the IHA may use under its 20% limit for management improvements (except as provided in paragraph (n)(2)(i) of this section), and the IHA needs to save a portion of its annual grant, in order to combine it with a portion of subsequent year(s) grants to fund the work item.

(2) The IHA shall invest replacement reserve funds so as to generate a return equal to or greater than the average 91-day Treasury bill rate.

(3) Interest earned on funds in the replacement reserve will not be added to the IHA's income in the determination of an IHA's operating subsidy eligibility, but must be used for eligible modernization costs.

(4) To the extent that its annual formula allocation and any unobligated balances of modernization funds are not adequate to meet emergency needs, an IHA must first use its replacement reserve, where funded, to meet emergency needs, before requesting funds from the reserve under § 950.606.

(5) An IHA is not required to use its replacement reserve for natural and other disasters.

(g) *Management improvement costs.*

(1) *General.* Management improvements that are development-specific or IHA-wide in nature are eligible costs where needed to upgrade the operation of the IHA's developments, sustain physical improvements at those developments or correct management deficiencies. An IHA's ongoing operating expenses are ineligible management improvement costs. For CIAP IHAs, management improvements may be funded as a single work item.

(2) *Eligible costs.* Eligible costs include:

(i) *General management improvement costs.* Eligible costs include general management improvement costs, such as: management, financial, and accounting control systems of the IHA; adequacy and qualifications of IHA personnel, including training; resident programs and services through the coordination of the provision of social services from tribal or local government or other public and private entities; resident and development security; resident selection and eviction; occupancy; rent collection; maintenance; and equal opportunity.

(ii) *Economic development costs.* Eligible costs include job training for residents and resident business

development activities, for the purpose of carrying out activities related to the modernization-funded management and physical improvements. HUD encourages IHAs, to the greatest extent feasible, to hire residents as trainees, apprentices, or employees to carry out the modernization program under this part, and to contract with resident-owned businesses for modernization work.

(iii) *Resident management costs.* Eligible costs include technical assistance to a resident council or resident management corporation (RMC), as defined in § 950.962, in order to: determine the feasibility of resident management to carry out management functions for a specific development or developments; train residents in skills directly related to the operations and management of the development(s) for potential employment by the RMC; train RMC board members in community organization, board development, and leadership; and assist in the formation of an RMC.

(iv) *Resident homeownership costs.* Eligible costs are limited to the study of the feasibility of converting rental to homeownership units and the preparation of an application for conversion to homeownership or sale of units.

(v) *Preventive maintenance system.* Eligible costs include the establishment of a preventive maintenance system or improvement of an existing system. A preventive maintenance system must provide for regular inspections of building structures, systems and units and determine the applicability of work eligible for operating funds (routine maintenance) and work eligible for modernization funding (non-routine maintenance).

(h) *Drug elimination costs.* Eligible costs include drug elimination activities involving management or physical improvements, as specified by HUD.

(i) *LBP costs.* Eligible costs include professional risk assessments and interim containment of family developments/buildings constructed before 1980, testing and abatement of family developments/buildings constructed before 1978, and costs for insurance coverage for pollution hazards associated with the testing, abatement, clean-up and disposal of LBP on applicable surfaces of family developments/buildings constructed before 1978.

(j) *Administrative costs.* Administrative costs necessary for the planning, design, implementation and monitoring of the physical and management improvements are eligible costs and include the following:

(1) *Salaries.* The salaries of non-technical and technical IHA personnel assigned full-time or part-time to modernization are eligible costs only where the scope and volume of the work are beyond that which could be reasonably expected to be accomplished by such personnel in the performance of their non-modernization duties. An IHA shall properly apportion to the appropriate program budget any direct charges for the salaries of assigned full- or part-time staff (e.g., to the CIAP, CGP or operating budget);

(2) *Employee benefit contributions.* IHA contributions to employee benefit plans on behalf of non-technical and technical IHA personnel are eligible costs in direct proportion to the amount of salary charged to the CIAP or CGP, as appropriate;

(3) *Preparation of CIAP or CGP required documents.*

(4) *Resident participation.* Eligible costs include those associated with ensuring the meaningful participation of residents in the development of the CIAP application or the CGP Annual Submission and Comprehensive Plan and the implementation and monitoring of the approved modernization program; and

(5) *Other administrative costs,* such as telephone and facsimile, as specified by HUD.

(k) *Audit costs (for CGP only).* Eligible costs are limited to the portion of the audit costs that are attributable to the modernization program.

(l) *Architectural/engineering and consultant fees.* Eligible costs include fees for planning, identification of needs, detailed design work, preparation of construction and bid documents and other required documents, LBP professional risk assessments and testing, and inspection of work in progress.

(m) *Relocation costs.* Eligible costs include relocation and other assistance for permanent and temporary relocation, as a direct result of rehabilitation, demolition or acquisition for a modernization-funded activity, where this assistance is required by 49 CFR part 24 or 24 CFR 950.117.

(n) *Cost limitations.* (1) *CIAP costs.* (i) *Management improvement costs.* Management improvement costs shall not exceed a percentage of the CIAP funds available to a Field Office in a particular FFY, as specified by HUD.

(ii) *Planning costs.* Planning costs are costs that are incurred before HUD approval of the CIAP application and that are related to developing the CIAP application or carrying out eligible modernization planning, such as detailed design work, preparation of

solicitations, and LBP professional risk assessment and testing. Planning costs may be funded as a single work item. If an IHA incurs planning costs without prior HUD approval, an IHA does so with the full understanding that the costs may not be reimbursed upon approval of the CIAP application. Planning costs shall not exceed 5 percent of the CIAP funds available to a Field Office in a particular FFY.

(2) *CGP costs.* (i) *Management improvement costs.* Notwithstanding the full fungibility of work items, an IHA shall not use more than a total of 20 percent of its annual grant for management improvement costs in account 1408, unless specifically approved by HUD.

(ii) *Administrative costs.* Notwithstanding the full fungibility of work items, an IHA shall not use more than a total of 10 percent of its annual grant on administrative costs in account 1410, excluding any costs related to lead-based paint or asbestos testing (whether conducted by force account employees or by a contractor), in-house architectural/engineering (A/E) work, or other special administrative costs required by tribal or State law, unless specifically approved by HUD.

(3) *Program benefit.* Where the physical or management improvement, including administrative cost, will benefit programs other than Indian housing, such as Section 8 or local revitalization programs, eligible costs are limited to the amount directly attributable to the Indian housing program.

(4) *No duplication.* Any eligible cost for an activity funded by CIAP or CGP shall not also be funded by any other HUD program.

(o) *Ineligible costs.* Ineligible costs include:

(1) Luxury improvements;

(2) Indirect administrative costs (overhead), as defined in OMB Circular A-87;

(3) Indian housing operating assistance;

(4) Direct provision of social services, through either force account or contract labor, from FFY 1996 and future FFYs funds, unless otherwise provided by law; and

(5) Other ineligible activities, as specified by HUD.

(p) *Expanded eligibility for FFY 1995 and prior year modernization funds.* The FFY 1995 Rescissions Act expanded the eligible activities that may be funded with CIAP or CGP assistance provided from FFY 1995 and prior FFY funds. Such activities include, but are not limited to:

(1) New construction or acquisition of additional Indian housing units, including replacement units;

(2) Modernization activities related to the Indian housing portion of housing developments held in partnership, or cooperation with non-Indian housing entities; and

(3) Other activities related to Indian housing, including activities eligible under the Urban Revitalization Demonstration (HOPE VI).

#### **§ 950.610 Modernization and energy conservation standards.**

All improvements funded under this part shall:

(a) Meet the modernization standards as prescribed by HUD;

(b) Incorporate cost-effective energy conservation measures, identified in the IHA's most recently updated energy audit, conducted pursuant to part 950, subpart K;

(c) Where changing or installing a new utility system, conduct a life-cycle cost analysis, reflecting installation and operating costs; and

(d) Provide decent, safe, and sanitary living conditions in IHA-owned and IHA-operated public housing.

#### **§ 950.612 Force account.**

(a) An IHA may undertake the activities using force account or contract labor, including contracting with an RMC, without prior HUD approval.

(b) If the entirety of modernization activity (including the planning and architectural design of the rehabilitation) is administered by the RMC, the IHA shall not retain for any administrative or other reason, any portion of the modernization funds provided, unless the IHA and the RMC provide otherwise by contract.

#### **§ 950.614 Initiation of modernization activities.**

After HUD has approved the modernization program and entered into an ACC amendment with the IHA, an IHA shall undertake the modernization activities and expenditures set forth in its approved CIAP budget or CGP Annual Statement/Five-Year Action Plan in a timely, efficient and economical manner. All approved funding must be obligated within two years of approval and expended within three years of approval unless HUD approves a longer time period in the IHA's implementation schedule, as set forth in the CIAP budget or CGP Annual Statement. HUD may approve a longer time period for such reasons as the large size of the grant or the complexity of the work.

#### **§ 950.616 Fund requisitions.**

To draw down modernization funds against the approved CIAP budget or CGP Annual Statement, as appropriate, an IHA shall comply with requirements prescribed by HUD.

#### **§ 950.618 Contracting requirements.**

In addition to the requirements specified in 24 CFR parts 85 and subpart B of this part, the following provisions apply:

(a) *Architect/engineer and other professional services contracts.* For CIAP only and notwithstanding 24 CFR 85.36(g), an IHA shall comply with HUD requirements to either:

(1) Where the proposed contract amount exceeds the HUD-established threshold, submit the contract for prior HUD approval before execution or issuance; or

(2) Where the proposed contract amount does not exceed the HUD-established threshold, certify that the scope of work is consistent with the originally approved modernization program, and that the amount is appropriate and does not result in the total HUD-approved CIAP budget being exceeded.

(b) *Assurance of completion.* For CIAP and CGP and notwithstanding 24 CFR 85.36(h), for each construction contract over \$100,000, the contractor shall furnish a bid guarantee from each bidder equivalent to 5% of the bid price; and one of the following:

(1) A performance and payment bond for 100 percent of the contract price; or

(2) Separate performance and payment bonds, each for 50% or more of the contract price; or

(3) A 20% cash escrow; or

(4) A 25% irrevocable letter of credit.

(c) *Construction solicitations.* For CIAP only and notwithstanding 24 CFR 85.36(g), an IHA shall comply with HUD requirements to either:

(1) Where the estimated contract amount exceeds the HUD-established threshold, submit a complete construction solicitation for prior HUD approval before issuance; or

(2) Where the estimated contract amount does not exceed the HUD-established threshold, certify receipt of the required architect's/engineer's certification that the construction documents accurately reflect HUD-approved work and meet the modernization and energy conservation standards and that the construction solicitation is complete and includes all mandatory items.

(d) *Contract awards.* (1) For CIAP only, an IHA shall obtain HUD approval of the proposed award of a contract if the contract work is inconsistent with

the originally approved modernization program or if the procurement meets the criteria set forth in 24 CFR 85.36(g)(2)(i) through (iv). In all other instances, an IHA shall make the award without HUD approval after the IHA has certified that:

- (i) The solicitation and award procedures were conducted in compliance with tribal, State or local laws and Federal requirements;
- (ii) The award does not meet the criteria in 24 CFR 85.36(g)(2)(i) through (iv) for prior HUD approval; and
- (iii) The contractor is not on the Lists of Parties Excluded from Federal Procurement or Nonprocurement Programs.

(2) For CGP only, an IHA shall obtain HUD approval of the proposed award of a contract if the procurement meets the criteria set forth in 24 CFR 85.36(g)(2)(i) through (iv).

(e) *Contract modifications.* For CIAP only and notwithstanding 24 CFR 85.36(g), except in an emergency endangering life or property, an IHA shall comply with HUD requirements to either:

(1) Where the proposed contract modification exceeds the HUD-established threshold, submit the proposed modification for prior HUD approval before issuance; or

(2) Where the proposed contract modification does not exceed the HUD-established threshold, certify that the proposed modification is within the scope of the contract and that any additional costs are within the total HUD-approved CIAP budget amount.

(f) *Construction requirements.* Where indicated by poor performance, an IHA may be required to submit to HUD periodic progress reports and, for prior HUD approval, construction completion documents above a HUD-specified amount. For CGP only, an IHA is notified of additional construction requirements by a notice of deficiency or a corrective action order.

#### **§ 950.620 On-site inspections.**

It is the responsibility of the IHA, not HUD, to provide, by contract or otherwise, adequate and competent supervisory and inspection personnel during modernization, whether work is performed by contract or force account labor, and with or without the services of an architect/engineer, to assure work quality and progress.

#### **§ 950.622 Fiscal closeout.**

(a) *Actual modernization cost certificate (AMCC).* Upon expenditure by the IHA of all funds, or termination by HUD of the activities funded in a modernization program, an IHA shall submit the AMCC, in a form prescribed

by HUD, to HUD for review and approval for audit. After audit verification, HUD shall approve the AMCC.

(b) *Audit.* The audit shall follow the guidelines prescribed in 24 CFR part 44, Non-Federal Government Audit Requirements. If the pre-audit or post-audit AMCC indicates that there are excess funds, an IHA shall immediately remit the excess funds as directed by HUD. If the pre-audit or post-audit AMCC discloses unauthorized or ineligible expenditures, an IHA shall immediately take such corrective actions as HUD may direct.

Comprehensive Improvement Assistance Program (For IHAs that Own or Operate Fewer than 250 Indian Housing Units)

#### **§ 950.630 Procedures for obtaining approval of a modernization program.**

(a) *HUD notification.* After modernization funds for a particular FFY become available, HUD shall publish in the Federal Register a notice of funding availability (NOFA) and the time frame for submission of the CIAP application, and other pertinent information.

(b) *IHA consultation with tribal/local officials and residents/homebuyers.* An IHA shall develop the application in consultation with tribal and local officials and with residents and homebuyers, as set forth in § 950.632.

(c) *IHA application.* An IHA shall submit to HUD an application, in a form prescribed by HUD. Where an IHA has not included all its developments in the CIAP application, HUD may not consider funding any nonemergency work at excluded developments or subsequently approve use of leftover funds at excluded developments.

(d) *Completeness review.* To be eligible for processing, an application must be physically received by HUD by the time and date specified in the NOFA. Immediately after the application deadline, HUD shall perform a completeness review to determine whether the application is complete, responsive to the NOFA, and acceptable for technical processing.

(1) If the application form or any other essential document, as specified in the NOFA, is missing, the IHA's application will be considered substantially incomplete and, therefore, ineligible for further processing. HUD shall immediately notify the IHA in writing.

(2) If other required documents, as specified in the NOFA, are missing or there is a technical mistake, such as no signature on a submitted form, HUD shall immediately notify the IHA in

writing to submit or correct the deficiency within a specified period of time from the date of HUD's written notification. This is not additional time to substantially revise the application. Deficiencies that may be corrected at this time are inadvertently omitted documents or clarifications of previously submitted material and other changes which are not of such a nature as to improve the competitive position of the application.

(3) If an IHA fails to submit or correct the items within the required time period, the IHA's application will be ineligible for further processing. HUD shall immediately notify the IHA in writing after this occurs.

(4) An IHA may submit an application for Emergency Modernization whenever needed.

(e) *Eligibility review.* (1) *Eligibility for processing.* To be eligible for processing each eligible development for which work is proposed must have reached the Date of Full Availability (DOFA) and be under ACC amendment at the time of CIAP application submission.

(2) *Eligibility for processing on reduced scope.* When the following conditions exist, an IHA will be reviewed on a reduced scope:

(i) *Section 504 compliance.* Where an IHA has not completed all required structural changes to meet the need for accessible units, as identified in the IHA's Section 504 needs assessment, the IHA is eligible for processing only for Emergency Modernization or physical work needed to meet Section 504 requirements.

(ii) *Lead-based paint (LBP) testing compliance.* Where an IHA has not complied with the statutory requirement to complete LBP testing on all pre-1978 family units, the IHA is eligible for processing only for Emergency Modernization or work needed to complete the testing.

(iii) *Fair Housing and Equal Opportunity (FHEO) compliance.* Where an IHA has not complied with any applicable FHEO requirements set forth in § 950.115, as evidenced by an enforcement action, finding or determination, the IHA is eligible for processing only for Emergency Modernization or for work needed to remedy civil rights deficiencies—unless the IHA is implementing a voluntary compliance agreement or settlement agreement designed to correct the area(s) of noncompliance. The enforcement actions, findings, or determinations that trigger limited eligibility are described in paragraphs (e)(2)(iii)(A) through (E) of this section:

(A) A pending proceeding against the IHA based upon a charge of

discrimination issued under the Fair Housing Act. A charge of discrimination is a charge under section 810(g)(2) of the Fair Housing Act (42 U.S.C. 3610(g)(2)), issued by the Department's General Counsel or legally authorized designee;

(B) A pending civil rights suit against the IHA, referred by the Department's General Counsel and instituted by the Department of Justice;

(C) Outstanding HUD findings of IHA noncompliance with civil rights statutes and executive orders under § 950.115, or implementing regulations, as a result of formal administrative proceedings;

(D) A deferral of the processing of applications from the IHA imposed by HUD under Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d-1) and HUD implementing regulations (24 CFR 1.8), the Attorney General's Guidelines (28 CFR 50.3), and procedures (HUD Handbook 8040.1), or under Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and HUD implementing regulations (24 CFR 8.57); or

(E) An adjudication of a violation under any of the authorities specified in § 950.115 in a civil action filed against the IHA by a private individual.

(f) *Technical processing.* After all CIAP applications are reviewed for eligibility, HUD shall categorize the eligible IHAs and their developments into two processing groups: Group 1 for Emergency Modernization; and Group 2 for Other Modernization. IHA developments may be included in both groups and the same development may be in each group. However, an IHA is only required to submit one CIAP application. Group 1 developments are not subject to the technical review rating and ranking and the long-term viability and reasonable cost determination. Group 2 developments are subject to the technical review rating and ranking and the long-term viability and reasonable cost determination. Preference will be given to IHAs which request assistance for developments that either have conditions that threaten the health or safety of the residents or have a significant number of vacant, substandard units, and which have demonstrated a capability of carrying out the proposed activities.

(g) *Rating on technical review factors.* After categorizing the eligible IHAs/developments into Group 1 and Group 2, HUD shall review and rate each Group 2 IHA on each of the following technical review factors:

(1) Extent and urgency of need, including need to comply with statutory, regulatory, or court-ordered deadlines;

(2) Extent of vacancies, where the vacancies are not due to insufficient demand;

(3) IHA's modernization capability;

(4) IHA's management capability;

(5) Degree of resident involvement in IHA operations;

(6) Degree of IHA activity in resident initiatives, including resident management, economic development, and drug elimination efforts;

(7) Degree of resident employment;

(8) Tribal/local government support for proposed modernization; and

(9) Such additional factors as the Secretary determines necessary and appropriate.

(h) *Ranking and selection for Joint Review.* After rating all Group 2 IHAs/developments, the Area ONAP shall then rank each Group 2 IHA based on its total score, list Group 2 IHAs in descending order, subject to confirmation of need and cost at Joint Review, and identify for Joint Review selection the highest IHA ranking applications in Group 2 and other Group 2 IHAs with lower ranking applications, but with high priority needs, which most reasonably approximate the amount of modernization which can be funded. High priority needs are nonemergency needs, but related to: health or safety; vacant, substandard units; structural or system integrity; or compliance with statutory, regulatory, or court-ordered deadlines. All Group 1 applications are automatically selected for Joint Review.

(i) *Joint review.* The purpose of the Joint Review is for HUD to discuss with an IHA the proposed modernization program, as set forth in the CIAP application, review long-term viability and cost reasonableness determinations, and determine the size of the grant, if any, to be awarded. HUD shall notify each IHA whose application has been selected for further processing as to whether Joint Review will be conducted on-site or off-site (e.g., by telephone or in-office meeting). An IHA shall prepare for Joint Review by preparing a draft CIAP budget, and reviewing the other items to be covered during Joint Review, as prescribed by HUD. If conducted on-site, Joint Review may include an inspection of the proposed physical work. IHAs not selected for Joint Review will be advised in writing of the reasons for non-selection.

(j) *Funding decisions.* After all Joint Reviews are completed, HUD shall adjust the IHAs, developments, and work items to be funded and the amounts to be awarded, on the basis of information obtained from Joint Reviews, environmental reviews, and FHEO review, and make the funding

decisions. An IHA will not be selected for CIAP funding if there is a duplication of funding. HUD shall select all bona fide emergencies in Group 1 before funding Group 2 applications. After funding announcement, HUD shall request a funded IHA to submit a CIAP budget, including an implementation schedule, and any other required documents, including the ACC amendment. IHAs not selected for funding will be advised in writing of the reasons for non-selection.

(k) *ACC amendment.* After HUD approval of the CIAP budget, HUD and the IHA shall enter into an ACC amendment in order for the IHA to draw down modernization funds. The ACC amendment shall require low-income use of the housing for not less than 20 years from the date of the ACC amendment (subject to sale of homeownership units in accordance with the terms of the ACC). The IHA Executive Director, where authorized by the Board of Commissioners and permitted by tribal or State law, may sign the ACC amendment on behalf of the IHA. HUD has the authority to condition an ACC amendment (e.g., to require an IHA to hire a modernization coordinator or contract administrator to administer its modernization program).

(l) *Declaration of trust.* As HUD may require, an IHA shall execute and file for record a Declaration of Trust as provided under the ACC to protect the rights and interests of HUD throughout the 20-year period during which the IHA is obligated to operate its developments in accordance with the ACC, the Act, and HUD regulations and requirements. A Declaration of Trust is not required for Mutual Help units.

(Approved by the Office of Management and Budget under control number 2577-0044. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a valid control number.)

#### **§ 950.632 Resident and homebuyer participation.**

An IHA shall establish a Partnership Process, as defined in § 950.102, to develop, implement, and monitor the CIAP. Before submission of the CIAP application, an IHA shall consult with the residents, the resident organization, or the resident management corporation (see subpart O of this part) (herein referred to as the resident) of the development(s) being proposed for modernization, regarding its intent to submit an application and to solicit resident comments. An IHA shall give residents a reasonable opportunity to present their views on the proposed modernization and alternatives to it and

shall give full and serious consideration to resident recommendations. An IHA shall respond in writing to the residents, indicating its acceptance or rejection of resident recommendations, consistent with HUD requirements and the IHA's own determination of efficiency, economy, and need. After HUD approval of the modernization program, an IHA shall inform the residents of the approved work items and its progress during implementation. Where HUD does not approve the modernization program, an IHA shall so inform the residents.

#### **§ 950.634 Budget revisions.**

(a) An IHA shall not incur any modernization cost in excess of the total HUD-approved CIAP budget. An IHA shall submit a budget revision, in a form prescribed by HUD, if the IHA plans to deviate from the originally approved modernization program, as it was competitively funded, by deleting or substantially revising approved work items or adding new work items that are unrelated to the originally approved modernization program.

(b) In addition to the provisions of paragraph (a) of this section, an IHA shall comply with the following requirements:

(1) An IHA is not required to obtain prior HUD approval if, in order to complete the originally approved modernization program, the IHA needs to delete or revise approved work items or add new related work items consistent with the original modernization program. In such case, an IHA shall certify that the revisions are necessary to carry out the approved work and do not result in substantial changes to the competitively funded modernization program.

(2) An IHA shall not incur any modernization cost on behalf of any development that is not covered by the original CIAP application.

(3) Where there are funds leftover after completion of the originally approved modernization program, an IHA may, without prior HUD approval, use the remaining funds to carry out other eligible modernization activities at developments covered by the original CIAP application.

#### **§ 950.636 Progress reports.**

For each six-month period ending March 31 and September 30, until completion of the modernization program or expenditure of all funds, an IHA shall submit a progress report, in a form prescribed by HUD, to the HUD Area ONAP. Where HUD determines that an IHA is having implementation

problems, HUD may require more frequent reporting.

#### **§ 950.638 Time extensions.**

An IHA shall not obligate or expend funds after the obligation or expenditure deadline date approved by HUD in the original implementation schedule without a time extension, as follows:

(a) *Certification.* An IHA may extend an obligation or expenditure deadline date no later than 30 calendar days after the existing deadline date, without prior HUD approval, for a time period commensurate with the delay, where the IHA certifies that the delay is due to reasons outside the IHA's control, such as:

(1) Need to use leftover funds from a completed modernization program for additional work;

(2) Unforeseen delays in contracting or contract administration;

(3) Litigation; and

(4) Delay by HUD or other institutions. Delay by the IHA's staff or Board of Commissioners or a change in the Executive Director is not considered to be outside of the IHA's control.

(b) *Prior HUD approval.* Where an IHA is unable to meet an obligation or expenditure deadline date and the delay is not due to reasons within the IHA's control, the IHA must request HUD approval of a time extension no later than 30 calendar days after the deadline date, to avoid recapture of funds. The request shall include an explanation of the delay, the steps taken to prevent future delay, and the requested extension.

#### **§ 950.640 HUD review of IHA performance.**

HUD shall periodically review IHA performance in carrying out its approved modernization program to determine compliance with HUD requirements, the quality of an IHA's inspections as evidenced by the quality of work, and the timeliness of the work. HUD's review may be conducted either in-office or on-site. Where conducted in-office, an IHA shall forward any requested documents to HUD for post-review. Where deficiencies are noted, an IHA shall take such corrective actions as HUD may direct.

Comprehensive Grant Program (For IHAs That Own or Operate 250 or More Indian Housing Units)

#### **§ 950.650 Determination of formula amount.**

(a) *Submission of formula characteristics report.* (1) *Formula characteristics report.* In its first year of participation in the CGP, each IHA shall verify and provide data to HUD, in a form and at a time to be prescribed by

HUD, concerning IHA and development characteristics, so that HUD can develop the IHA's annual funding allocation under the CGP in accordance with § 950.604(e) and (f). If an IHA fails to submit to HUD the formula characteristics report by the prescribed deadline, HUD will use the data that it has available concerning IHA and development characteristics for purposes of calculating the IHA's formula share. After its first year of participation in the CGP, an IHA is not required to submit formula characteristics report data to HUD, but is required to respond to data transmitted by HUD if there have been changes to its inventory from that previously reported, or when requested by HUD. On an annual basis, HUD will transmit to the IHA the formula characteristics report that reflects the data that will be used to determine the IHA's formula share. The IHA will have at least 30 calendar days to review and advise HUD of errors in this HUD report. Necessary adjustments will be made to the IHA's data before the formula is run for the current FFY.

(2) *IHA Board Resolution.* In its first year of participation in the CGP, the IHA must include with its formula characteristics report under paragraph (a)(1) of this section, a resolution adopted by the IHA Board of Commissioners approving the report, and certifying that the data contained in the formula characteristics report are accurate.

(b) *HUD notification of formula amount; appeal rights.* (1) *Formula amounts notification.* After HUD determines an IHA's formula allocation under § 950.604(e) and (f) based upon the IHA, development, and community characteristics, it shall notify the IHA of its formula amount and provide instructions on the Annual Submission in accordance with §§ 950.652(a) and 950.656;

(2) *Appeal based upon unique circumstances.* An IHA may appeal in writing HUD's determination of its formula amount within 60 calendar days of the date of HUD's determination on the basis of "unique circumstances." The IHA shall indicate what is unique, specify the manner in which it is different from all other IHAs participating in the CGP, and provide any necessary supporting documentation. HUD shall render a written decision on an IHA's appeal under this paragraph within 60 calendar days of the date of its receipt of the IHA's request for an appeal. HUD shall publish in the Federal Register a description of the facts supporting any successful appeals based upon "unique

circumstances." Any adjustments resulting from successful appeals in a particular FFY under this paragraph shall be made from the subsequent years' allocation of funds under this part;

(3) *Appeal based upon error.* An IHA may appeal in writing HUD's determination of its formula amount within 60 calendar days of the date of HUD's determination on the basis of an error. The IHA may appeal on the basis of error the correctness of data in the formula characteristics report. The IHA shall describe the nature of the error and provide any necessary supporting documentation. HUD shall respond to the IHA's request within 60 calendar days of the date of its receipt of the IHA's request for an appeal. Any adjustment resulting from successful appeals in a particular FFY under this paragraph shall be made from subsequent years' allocation of funds under this part;

(c) *IHAs determined to be high risk.* If an IHA is determined to have serious deficiencies in accordance with § 950.135, or if the IHA fails to meet, or to make reasonable progress toward meeting, the goals previously established in its management improvement plan under § 950.135, HUD may designate the IHA as high risk. If HUD designates the IHA as high risk with respect to modernization, HUD may withhold some or all of the IHA's annual grant; HUD may declare a breach of the grant agreement with respect to all or some of the IHA's functions, so that the IHA or a particular function of the IHA may be administered by another entity; or HUD may take other sanctions authorized by law or regulation.

**§ 950.652 Comprehensive plan (including Five-Year Action Plan).**

(a) *Submission.* As soon as possible after modernization funds first become available for allocation under this subpart, HUD shall notify IHAs in writing of their formula amount. For planning purposes, IHAs may use the amount they received under CGP in the prior year in developing their comprehensive plan, or they may wait for the annual HUD notification of formula amount under § 950.650(b)(1).

(b)(1) *Resident participation.* An IHA is required to develop, implement, monitor, and annually amend portions of its comprehensive plan in consultation with residents of the developments covered by the comprehensive plan, and with democratically elected resident groups. In addition, the IHA shall also consult with resident management corporations (RMCs) to the extent that an RMC

manages a development covered by the comprehensive plan. The IHA, in partnership with the residents, shall develop and implement a process for resident participation that ensures that residents are involved in a meaningful way in all phases of the CGP. Such involvement shall include implementing the Partnership Process as a critical element of the CGP.

(2) *Establishment of Partnership Process.* The IHA, in partnership with the residents of the developments covered by the plan (and which may include resident leaders, resident organizations, resident advisory councils/boards and RMCs) must establish a Partnership Process to develop and implement the goals, needs, strategies, and priorities identified in the Comprehensive Plan. After residents have organized to participate in the CGP, they may decide to establish a volunteer advisory group of experts in various professions to assist them in the CGP Partnership Process. The Partnership Process shall be designed to achieve the following:

(i) To assure that residents are fully briefed and involved in developing the content of, and monitoring the implementation of, the Comprehensive Plan including, but not limited to, the physical and management needs assessments, viability analysis, five-year action plan, and annual statement. If necessary, the IHA shall develop and implement capacity building strategies to ensure meaningful resident participation in CGP. Such technical assistance efforts for residents are eligible management improvement costs under CGP;

(ii) To enable residents to participate, on an IHA-wide or area-wide basis, in ongoing discussions of the comprehensive plan and strategies for its implementation, and in all meetings necessary to ensure meaningful participation.

(3) *Public notice.* Within a reasonable amount of time before the advance meeting for residents and duly elected resident organizations under paragraph (b)(4) of this section, and the public hearing under paragraph (b)(5) of this section, the IHA shall provide public notice of the advance meeting and the public hearing in a manner determined by the IHA and which ensures notice to all duly elected resident organizations;

(4) *Advance meeting for residents and duly elected resident organizations.* The IHA shall hold, within a reasonable amount of time before the public hearing under paragraph (b)(5) of this section, a meeting for residents and duly elected resident organizations at which the IHA shall explain the components of

the comprehensive plan. The meeting shall be open to all residents and duly elected resident organizations;

(5) *Public Hearing.* The IHA shall hold at least one public hearing, and any appropriate number of additional hearings, to present information on the comprehensive plan/annual submission and the status of prior approved programs. The public hearing shall provide ample opportunity for residents, tribal government officials, and other interested parties to express their priorities and concerns. The IHA shall give full consideration to the comments and concerns of residents, tribal government officials, and other interested parties.

(c) *Tribal/local government participation.* An IHA shall consult with and provide information to appropriate tribal and local government officials with respect to the development of the comprehensive plan. In the case of an IHA with developments in multiple jurisdictions, the IHA may meet this requirement by consulting with an advisory group representative of all the jurisdictions. At a minimum, such consultation shall include providing such officials with:

(1) Advance written notice of the public hearing required under paragraph (b)(5) of this section;

(2) A copy of the summary of total preliminary estimated costs to address physical needs by each development and management/operations needs IHA-wide, a specific description of the IHA's process for maximizing the level of participation by residents, a summary of the general issues raised on the plan by residents and others during the public comment process, and the IHA's response to the general issues. IHA records, such as minutes of planning meetings or resident surveys, shall be maintained in the IHA's files and made available to residents, resident organizations, and other interested parties upon request; and

(3) An opportunity to express their priorities and concerns to ensure due consideration in the IHA's planning process.

(d) *Contents of Comprehensive Plan.* The comprehensive plan shall identify all of the physical and management improvements needed for an IHA and all of its developments, and that represent needs eligible for funding under § 950.608. The plan shall also include preliminary estimates of the total cost of these improvements. The plan shall set forth general strategies for addressing the identified needs, and highlight any special strategies, such as major redesign or partial demolition of a development, that are necessary to



ensure the long-term physical and social viability of the development. Where long-term physical and social viability of the development is dependent upon revitalization of the surrounding neighborhood in the provision of or coordination of public services, or the consolidation or coordination of drug prevention and other human service initiatives, the IHA shall identify these needs and strategies. Each comprehensive plan shall contain the following elements:

(1) *Executive summary.* An IHA shall include as part of its comprehensive plan an executive summary to facilitate review and comprehension by development residents and by the public. The executive summary shall include:

(i) A summary of total preliminary estimated costs to address physical needs by each development and IHA-wide physical and management needs; and

(ii) A specific description of the IHA's process for maximizing the level of participation by residents during the development, implementation, and monitoring of the comprehensive plan, a summary of the general issues raised on the plan by residents and others during the public comment process, and the IHA's response to the general issues. IHA records, such as minutes of planning meetings or resident surveys, shall be maintained in the IHA's files and made available to residents, duly elected resident organizations, and other interested parties, upon request;

(2) *Physical needs assessment.* (i) *Requirements.* The physical needs assessment identifies all of the work that an IHA would need to undertake to bring each of its developments up to the modernization and energy conservation standards, as required by the Act, to comply with lead-based paint testing and abatement requirements under § 950.120(g), and to comply with other program requirements under § 950.120. The physical needs assessment is completed without regard to the availability of funds, and shall include the following information with respect to each of an IHA's developments:

(A) A brief summary of the physical improvements necessary to bring each development to a level at least equal to the modernization and energy conservation standards set forth in § 950.610, to comply with the lead-based paint testing and abatement requirements under § 950.120(g), and to comply with other program requirements under § 950.120. The IHA also should indicate the relative urgency of need. If the IHA has no physical improvement needs at a particular

development at the time it completes its comprehensive plan, it must so indicate. Similarly, if the IHA intends to demolish, partially demolish, convert, or dispose of a development (or units within a development), it must so indicate in the summary of physical improvements;

(B) The replacement needs of equipment systems and structural elements that will be required to be met (assuming routine and timely maintenance is performed) during the period covered by the action plan;

(C) A preliminary estimate of the cost to complete the physical work; and

(D) In addition, the IHA shall provide with respect to vacant or non-homebuyer-occupied Turnkey III units, the estimated number of units that the IHA is proposing for substantial rehabilitation and subsequent sale, in accordance with § 950.608(d)(3).

(ii) *Sources of data.* The IHA shall identify in its needs assessment the sources from which it derived data to develop the physical needs assessment under this paragraph (d)(2), and shall retain such source documents in its files.

(3) *Management needs assessment.* (i) *Requirements.* The plan shall include a comprehensive assessment of the improvements needed to upgrade the management and operation of the IHA and of each viable development, so that decent, safe, and sanitary living conditions will be provided. The management needs assessment shall include the following, with the relative urgency of need indicated:

(A) An identification of the most current needs related to the following areas (to the extent that any of these needs is addressed in a HUD-approved management improvement plan, the IHA may simply include a cross-reference to these documents):

(1) The management, financial, and accounting control systems of the IHA;

(2) The adequacy and qualifications of personnel employed by the IHA in the management and operation of its developments, for each significant category of employment;

(3) The adequacy and efficacy of:

(i) Resident programs and services;

(ii) Resident and development

security;

(iii) Resident selection and eviction;

(iv) Occupancy;

(v) Maintenance;

(vi) Resident management and resident capacity building programs;

(vii) Resident opportunities for employment and business development and other self-sufficiency opportunities for residents; and

(viii) Homeownership opportunities for residents.

(B) Any additional deficiencies identified through audits and HUD monitoring reviews that are not addressed under paragraph (e)(3)(i)(A) of this section. To the extent that any of these is addressed in a HUD-approved management improvement plan, the IHA may include a cross-reference to these documents;

(C) Any other management and operations needs that the IHA wants to address at the IHA-wide or development level; and

(D) An IHA-wide preliminary cost estimate for addressing all the needs identified in the management needs assessment, without regard to the availability of funds.

(ii) *Sources of data.* The IHA shall identify in its needs assessment the sources from which it derived data to develop the management needs assessment under paragraph (d)(3) of this section, and shall retain such source documents in its files.

(4) *Demonstration of long-term physical and social viability.* (i) *General.*

The plan shall include, on a development-by-development basis, an analysis of whether completion of the improvements and replacements identified under paragraphs (e)(2) and (e)(3) of this section will reasonably ensure the long-term physical and social viability, including achieving structural/system soundness and full occupancy, of the development at a reasonable cost. For cost reasonableness, the IHA shall determine whether the unfunded hard costs satisfy the definition of "reasonable cost." Where the IHA wishes to fund a development, for other than emergencies, where hard costs exceed that reasonable cost, the IHA shall submit written justification to the Field Office. If the Field Office agrees with the IHA's request, the Field Office shall forward its recommendation to Headquarters for final decision. Where the estimated per unit unfunded hard cost is equal to or less than the per unit TDC for the smallest bedroom size at the development, no further computation of the TDC limit is required. The IHA shall keep documentation in its files to support all cost determinations. The Field Office will review cost reasonableness as part of its review of the Annual Submission and the Performance and Evaluation Report. As necessary, HUD will review the IHA's documentation in support of its cost reasonableness, taking into account broader efforts to revitalize the neighborhoods in which the development is located;

(ii) *Determination of non-viability.* When an IHA's analysis of a development, under paragraph (e) of



this section, establishes that completion of the identified improvements and replacements will not result in the long-term physical and social viability of the development at a reasonable cost, the IHA shall not expend CGP funds for the development, except for emergencies and essential nonroutine maintenance necessary to maintain habitability until residents can be relocated. The IHA shall specify in its comprehensive plan the actions it proposes to take with respect to the nonviable development (e.g., demolition or disposition under subpart M of this part).

(5) *Five-Year Action Plan.* (i) *General.* The comprehensive plan shall include a rolling five-year action plan to carry out the improvements and replacements (or a portion thereof) identified under paragraphs (e)(2) and (e)(3) of this section. In developing its five-year action plan, the IHA shall assume that the current year funding or formula amount will be available for each year of its five-year action plan, whichever the IHA is using for planning purposes, plus the IHA's estimate of the funds that will be available from other sources, such as tribal, state, and local governments. All activities specified in an IHA's five-year action plan are contingent upon the availability of funds.

(ii) *Requirements.* Under the action plan, an IHA must indicate how it intends to use the funds available to it under the CGP to address the deficiencies, or a portion of the deficiencies, identified under its physical and management needs assessments, as follows:

(A) *Physical condition.* With respect to the physical condition of an IHA's developments, an IHA must indicate in its action plan how it intends to address, over a five-year period, the deficiencies (or a portion of the deficiencies) identified in its physical needs assessment so as to bring each of its developments up to a level at least equal to the modernization and energy conservation standards. This would include specifying the work to be undertaken by the IHA in major work categories (e.g., kitchens, electrical systems, etc.); establishing priorities among the major work categories by development and year based upon the relative urgency of need; and estimating the cost of each of the identified major work categories. In developing its action plan, an IHA shall give priority to the following:

(1) Activities required to correct emergency conditions;

(2) Activities required to meet statutory (or other legally mandated) requirements;

(3) Activities required to meet the needs identified in the Section 504 needs assessment within the regulatory timeframe; and

(4) Activities required to complete lead-based paint testing and abatement requirements.

(B) *Management and operations.* An IHA shall address in its action plan the management and operations deficiencies (or a portion of the deficiencies) identified in its management needs assessment, as follows:

(1) With respect to the management and operations needs of the IHA, the IHA shall identify how it intends to address with CGP funds, if necessary, the deficiencies (or a portion thereof) identified in its management needs assessment, including work identified through audits, HUD monitoring reviews, and self-assessments (this would include establishing priorities based upon the relative urgency of need); and

(2) A preliminary IHA-wide cost estimate, by major work category.

(iii) *Procedure for maintaining current Five-Year Action Plan.* The IHA shall maintain a current Five-Year Action Plan by annually amending its Five-Year Action Plan, in conjunction with the Annual Submission;

(6) *Tribal/local government statement.* The Comprehensive Plan shall include a statement signed by the chief executive officer of the appropriate governing body (or in the case of an IHA with developments in multiple jurisdictions, from the CEO of each such jurisdiction), certifying as to the following:

(i) The IHA developed the comprehensive plan/five-year action plan or amendments thereto in consultation with officials of the appropriate governing body and with development residents covered by the comprehensive plan/five-year action plan, in accordance with the requirements of paragraphs (b) and (c) of this section;

(ii) The comprehensive plan/five-year action plan or amendments thereto are consistent with the appropriate governing body's assessment of its low-income housing needs and that the appropriate governing body will cooperate in providing resident programs and services; and

(iii) The IHA's proposed drug elimination activities are coordinated with, and supportive of, local drug elimination strategies and neighborhood improvement programs, if applicable.

(7) *IHA resolution.* The plan shall include a resolution, in a form prescribed by HUD, adopted by the IHA

Board of Commissioners, and signed by the Board Chairman of the IHA, approving the comprehensive plan or any amendments.

(e) *Amendments to the Comprehensive Plan.* (1) *Extension of time for performance.* An IHA shall have the right to amend its comprehensive plan (including the action plan) to extend the time for performance whenever HUD has not provided the amount of assistance set forth in the comprehensive plan or has not provided the assistance in a timely manner.

(2) *Amendments to needs assessments.* The IHA shall amend its plan by revising its needs assessments whenever it proposes to carry out activities in its five-year action plan or annual statement that are not reflected in its current needs assessments (except in the case of emergencies). The IHA may propose an amendment to its needs assessments, in connection with the submission of its annual submission (see § 950.656(b)), or at any other time. These amendments shall be reviewed by HUD in accordance with § 950.654;

(3) *Six-year revision of Comprehensive Plan.* Every sixth year following the initial year of participation, the IHA shall submit to HUD, with its annual submission, a complete update of its comprehensive plan. An IHA may elect to revise some or all parts of the comprehensive plan more frequently.

(4) *Annual revision of Five-Year Action Plan.* Annually, the IHA shall submit to HUD, with its annual submission, an update of its five-year action plan, eliminating the previous year and adding an additional year. The IHA shall identify changes in work categories (other than those included in the new fifth year) from the previous year five-year action plan when making this Annual Submission.

(5) *Required submissions.* Any amendments to the comprehensive plan under this section shall be submitted with the IHA resolution under § 950.652(e)(7).

(f) *Prerequisite for receiving assistance.* (1) *Prohibition of assistance.* No financial assistance, except for emergency work to be funded under §§ 950.604(b) and 950.606, and for modernization needs resulting from disasters under § 950.604(b), may be made available under this subpart unless HUD has approved a comprehensive plan submitted by the IHA that meets the requirements of § 950.652. An IHA that has failed to obtain approval of its comprehensive plan by the end of the FFY shall have its formula allocation for that year (less

any formula amounts provided to the IHA for emergencies) added to the subsequent year's appropriation of funds for grants under this part. HUD shall allocate such funds to PHAs and IHAs participating in the CGP in accordance with the formula under § 950.604(e) and (f) in the subsequent FFY. An IHA that elects in any FFY not to participate in the CGP under this subpart may participate in the CGP in subsequent FFYs.

(2) *Requests for emergency assistance.* An IHA may receive funds from its formula allocation to address emergency modernization needs even if HUD has not approved the IHA's comprehensive plan. To request such assistance, the IHA shall submit to HUD a request for funds in such form as HUD may prescribe, including any documentation necessary to support its claim that an emergency exists. HUD shall review the request and supporting documentation to determine if it meets the definition of "emergency work," as set forth in § 950.102.

**§ 950.654 HUD review and approval of comprehensive plan (including Five-Year Action Plan).**

(a) *Submission of comprehensive plan.* (1) Upon receipt of a comprehensive plan from an IHA, HUD shall determine whether:

(i) The plan contains each of the required components specified at § 950.652; and

(ii) If applicable, the IHA has submitted any additional information or assurances required as a result of HUD monitoring, findings of inadequate IHA performance, audit findings, or civil rights compliance findings.

(2) *Acceptance for review.* If the IHA has submitted a Comprehensive Plan (including the action plan) that meets the criteria specified in paragraph (a)(1) of this section, HUD shall accept the Comprehensive Plan for review, within 14 calendar days of its receipt in the Area ONAP. The IHA shall be notified in writing that the plan has been accepted by HUD, and that the 75-day review period is proceeding.

(3) *Time period for review.* A Comprehensive Plan that is accepted by HUD for review shall be considered to be approved unless HUD notifies the IHA in writing, postmarked within 75 calendar days of the date of HUD's receipt of the Comprehensive Plan for review, that HUD has disapproved the plan. HUD shall not disapprove a Comprehensive Plan on the basis that it cannot complete its review within the 75-day deadline.

(4) *Rejection of Comprehensive Plan.* If an IHA has submitted a

Comprehensive Plan (including the action plan) that does not meet the requirements of paragraph (a)(1) of this section, HUD shall notify the IHA within 14 calendar days of its receipt that HUD has rejected the plan for review. In such case, HUD shall indicate the reasons for rejection, the modifications required to qualify the Comprehensive Plan for HUD review, and the deadline date for receipt of any modifications.

(b) *HUD approval of Comprehensive Plan (including action plan).* (1) A Comprehensive Plan (including the action plan) that is accepted by HUD for review in accordance with paragraph (a) of this section shall be considered to be approved, unless HUD notifies the IHA in writing, postmarked within 75 days of the date of HUD's receipt of the Comprehensive Plan for review, that HUD has disapproved the plan, indicating the reasons for disapproval, and the modifications required to make the Comprehensive Plan approvable. The IHA shall re-submit the Comprehensive Plan to HUD, in accordance with the deadline established by HUD, which may allow up to 75 calendar days before the end of the FFY for HUD review. If the revised plan is disapproved by HUD following its resubmission, or the IHA fails to resubmit the plan by the deadline established by HUD, any funds that would have been allocated to the IHA shall be added to the subsequent year's appropriation of funds for grants under this subpart. HUD shall allocate such funds to IHAs and PHAs participating in the CGP in accordance with the formula under 24 CFR § 950.604 and 968.103. HUD shall not disapprove a Comprehensive Plan on the basis that HUD cannot complete its review under this section within the 75-day deadline.

(2) HUD shall approve the comprehensive plan except where it makes a determination in accordance with one or more of the following:

(i) Comprehensive plan is incomplete in significant matters;

(ii) Identified needs are plainly inconsistent with facts and data;

(A) Identified physical improvements and replacements are inadequate;

(B) Identified management improvements are inadequate;

(C) Proposed physical and management improvements fail to address identified needs;

(iii) Action plan is plainly inappropriate to meeting identified needs;

(iv) Inadequate demonstration of long-term viability at reasonable cost; or

(v) Contradiction of tribal/local government certification or IHA resolution.

(c) *Effect of HUD approval of Comprehensive Plan.* After HUD approves the Comprehensive Plan (including the Five-Year Action Plan), or any amendments to the plan, it shall be binding upon HUD and the IHA, until such time as the IHA submits, and HUD approves, an amendment to its plan. The IHA is expected to undertake the work set forth in the Annual Statement. However, the IHA may undertake any of the work identified in any of the other four years of the latest approved Five-Year Action Plan, current approved Annual Statement or previously approved CIAP budgets, without further HUD approval. Actual uses of the funds are to be reflected in the IHA annual Performance and Evaluation Report for each grant. See § 950.658. HUD encourages the IHA to inform the residents of significant changes (such as changes in scope of work or whenever it moves work items within the approved Five-Year Action Plan). The IHA shall retain documentation of that information in its files. If HUD determines as a result of an audit or monitoring findings that an IHA has provided false or substantially inaccurate data in its Comprehensive Plan/Annual Submission or has circumvented the intent of the program, HUD may condition the receipt of assistance, in accordance with § 950.660. Moreover, in accordance with 18 U.S.C. 1001, any individual or entity who knowingly and willingly makes or uses a document or writing containing any false, fictitious, or fraudulent statement or entry, in any matter within the jurisdiction of any department or agency of the United States, shall be fined not more than \$10,000 or imprisoned for not more than five years, or both.

**§ 950.656 Annual submission of activities and expenditures.**

(a) *General.* The Annual Submission is a collective term for all documents that the IHA shall submit to HUD for review and approval before accessing the current FFY grant funds. Such documents include the Annual Statement, Work Statements for years two through five of the Five-Year Action Plan, local government statement, IHA Board Resolution, materials demonstrating the partnership process, and any other documents as prescribed by HUD. For planning purposes, an IHA may use either the amount of funding received in the current year or the actual formula amount provided in HUD's notification under § 950.650 in

developing the Five-Year Action Plan for presentation at the resident meetings and public hearing. Work Statements cover the second through the fifth years of the Five-Year Action Plan and set forth the major work categories and costs, by development or IHA-wide, that the IHA intends to undertake in each year of years two through five. In preparing these Work Statements, the IHA shall assume that the current FFY formula amount will be available in each year of years two through five. The Work Statements for all five years will be at the same level of detail so that the IHA may interchange work items as discussed in § 950.652. An IHA may budget up to 8 percent of its annual grant in a contingency account for cost overruns.

(b) *Submission.* After receiving HUD notification of the formula amount estimating how much funding will be available from other sources, such as State and tribal governments, and determining its activities and costs based on the current FFY formula amount, the IHA shall submit its Annual Submission.

(c) *Acceptance for review.* (1) Upon receipt of an Annual Submission from an IHA, HUD shall determine whether:

(i) The Annual Submission contains each of the required components; and  
(ii) The IHA has submitted any additional information or assurances required as a result of HUD monitoring, findings of inadequate IHA performance, audit findings, and civil rights compliance findings.

(2) If the IHA has submitted a complete Annual Submission and all required information and assurances, HUD will accept the submission for review, as of the date of receipt. If the IHA has not submitted all required material, HUD will promptly notify the IHA that it has disapproved the submission, indicating the reasons for disapproval, the modifications required to qualify the Annual Submission for HUD review, and the date by which such modifications shall be received by HUD.

(d) *Resident and local government participation.* An IHA is required to develop its Annual Submission, including any proposed amendments to its Comprehensive Plan as provided in § 950.652, in consultation with officials of the appropriate governing body (or in the case of an IHA with developments in multiple jurisdictions, in consultation with the CEO of each such jurisdiction or with an advisory group representative of all jurisdictions) and with residents and duly elected resident organizations of the developments

covered by the Comprehensive Plan, as follows:

(1) *Public notice.* Within a reasonable amount of time before the advance meeting for residents under paragraph (d)(2) of this section, and the public hearing under paragraph (d)(3) of this section, the IHA shall annually provide public notice of the advance meeting and the public hearing in a manner determined by the IHA and that ensures notice to all duly elected resident organizations;

(2) *Advance meeting with residents.* The IHA shall at least annually hold a meeting open to all residents and duly elected resident organizations. The advance meeting shall be held within a reasonable amount of time before the public hearing under paragraph (d)(3) of this section. The IHA will provide residents with information concerning the contents of the IHA's Five-Year Action Plan (and any proposed amendments to the IHA's Comprehensive Plan to be submitted with the Annual Submission) so that residents can comment adequately at the public hearing on the contents of the Five-Year Action Plan and any proposed amendments to the Comprehensive Plan.

(3) *Public hearing.* The IHA shall annually hold at least one public hearing, and any appropriate number of additional hearings, to present information on the Annual Submission and the status of prior approved programs. The public hearing shall provide ample opportunity for residents of the developments covered by the Comprehensive Plan, officials of the appropriate governing body, and other interested parties, to express their priorities and concerns. The IHA shall give full consideration to the comments and concerns of residents, local government officials, and other interested parties in developing its Five-Year Action Plan, or any amendments to its Comprehensive Plan.

(4) *Expedited scheduling.* IHAs are encouraged to hold the meeting with residents and duly elected resident organizations under paragraph (d)(2) of this section, and the public hearing under paragraph (d)(3) of this section, between July 1 (i.e., after the end of the program year—June 30) and September 30, using the formula amount for the current FFY. If an IHA elects to use such expedited scheduling, it shall explain at the meeting with residents and duly elected resident organizations and at the public hearing that the current FFY amount is not the actual grant amount for the subsequent year, but is rather the amount used for planning purposes. It shall also explain that the Five-Year

Action Plan will be adjusted when HUD provides notification of the actual formula amount, and explain which major work categories at which developments may be added or deleted to adjust for the actual formula amount and that any added work categories/developments will come from the Comprehensive Plan.

(e) *Contents of Annual Submission.* The Annual Statement for each year shall include, for each development or on an IHA-wide basis for management improvements or certain physical improvements for which work is to be funded out of that year's grant:

(1) A list of development accounts with an identification of major work categories;

(2) The cost for each major work category, as well as a summary of cost by development account;

(3) The IHA-wide or development-specific management improvements to be undertaken during the year;

(4) For each development and for any management improvements not covered by a HUD-approved management improvement plan, a schedule for the use of current year funds, including target dates for the obligation and expenditure of the funds (see § 950.614);

(5) A summary description of the actions to be taken with non-CGP funds to meet physical and management improvement needs that have been identified by the IHA in its needs assessments;

(6) Documentation supporting the IHA's actions in carrying out its responsibilities under the National Environmental Policy Act and other related authorities in accordance with § 950.120(a) and (b);

(7) Other information, as specified by HUD and approved by OMB under the Paperwork Reduction Act; and

(8) An IHA resolution approving the Annual Submission or any amendments thereto, as set forth in § 950.652.

(f) *Additional submissions with Annual Submission.* An IHA shall submit with the Annual Submission any amendments to the Comprehensive Plan, as set forth in § 950.652, and such additional information as may be prescribed by HUD. HUD shall review any proposed amendments to the Comprehensive Plan in accordance with review standards under § 950.654.

(g) *HUD review and approval of Annual Submission.* (1) *General.* An Annual Submission accepted in accordance with paragraph (a) of this section shall be considered to be approved, unless HUD notifies the IHA in writing, postmarked within 75 calendar days of the date that HUD receives the Annual Submission for

review under paragraph (c) of this section, that HUD has disapproved the Annual Submission, indicating the reasons for disapproval, the modifications required to make the Annual Submission approvable, and the date by which such modifications shall be received by HUD. HUD may request additional information (e.g., for eligibility determinations) to facilitate review and approval of the Annual Submission during the 75-day review period. HUD shall not disapprove an Annual Submission on the basis that HUD cannot complete its review under this section within the 75-day deadline;

(2) *Bases for disapproval for Annual Submission.* HUD shall approve the Annual Submission, except when:

(i) *Plainly inconsistent with Comprehensive Plan.* HUD determines that the activities and expenditures proposed in the Annual Submission are plainly inconsistent with the IHA's approved Comprehensive Plan;

(ii) *Contradiction of IHA resolution.* HUD has evidence that tends to challenge, in a substantial manner, the certifications contained in the board resolution, as required by § 950.672(d)(7).

(h) *Amendments to Annual Statement.* The IHA shall advise HUD of all changes to the IHA's approved Annual Statement in its Performance and Evaluation Report submitted under § 950.658. The IHA shall submit to HUD for prior approval any additional work categories (except for emergency work) that are not within the IHA's approved Five-Year Action Plan.

(i) *Failure to obligate formula funding and extension of time for performance.*

(1) *Failure to obligate formula funds.* If the IHA fails to obligate formula funds within the approved or extended time period, the IHA may be subject to an alternative management strategy, which may involve third-party oversight or administration of the modernization function. HUD would only require such action after a corrective action order had been issued under § 950.660 and the IHA failed to comply with the order. HUD could then require an alternative management strategy in a corrective action order. An IHA may appeal in writing the corrective action order requiring an alternative management strategy within 30 calendar days of that order. HUD Headquarters shall render a written decision on an IHA's appeal within 30 calendar days of the date of its receipt of the IHA's appeal.

(2) *Extension of time for performance.* An IHA may extend the target dates for fund obligation and expenditure in the approved Annual Statement whenever any delay outside the IHA's control

occurs, as specified by HUD, and the extension is made in a timely manner. Such revision is subject to HUD review under § 950.660 as to the IHA's continuing capacity. HUD shall not review as to an IHA's continuing capacity any revisions to an IHA's Comprehensive Plan and related statements when the basis for the revision is that HUD has not provided the amount of assistance set forth in the Annual Submission, or has not provided such assistance in a timely manner.

(j) *ACC Amendment.* After HUD approval of each year's Annual Submission, HUD and the IHA shall enter into an ACC amendment in order to draw down modernization funds. The ACC amendment shall require low-income use of housing for not less than 20 years from the date of the ACC amendment (subject to sale of homeownership units in accordance with the terms of the ACC).

(k) *Declaration of Trust.* As HUD may require, the IHA shall execute and file for record a Declaration of Trust as provided under the ACC to protect the rights and interests of HUD throughout the 20-year period during which the IHA is obligated to operate its developments in accordance with the ACC, the Act, and HUD regulations and requirements. A Declaration of Trust is not required for Mutual Help units.

#### **§ 950.658 IHA Performance and Evaluation Report.**

For any FFY in which an IHA has received assistance under this subpart, the IHA shall submit a Performance and Evaluation Report, in a form and at a time to be prescribed by HUD, describing its use of assistance in accordance with the approved Annual Statement. The IHA shall make reasonable efforts to notify residents and officials of the appropriate governing body of the availability of the draft report, make copies available to residents in the development office, and provide residents with at least 30 calendar days in which to comment on the report.

#### **§ 950.660 HUD review of IHA performance.**

(a) *HUD determination.* At least annually, HUD shall carry out such reviews of the performance of each IHA as may be necessary or appropriate to make the determinations required by this paragraph (a), taking into consideration all available evidence.

(1) *Conformity with Comprehensive Plan.* HUD will determine whether the IHA has carried out its activities under this subpart I in a timely manner and in accordance with its Comprehensive Plan.

(2) *Continuing capacity.* HUD will determine whether the IHA has a continuing capacity to carry out its Comprehensive Plan in a timely manner. After the first full operational year of CGP, CIAP experience will not be taken into consideration except when the IHA has not yet had comparable experience under the CGP.

(3) *Reasonable progress.* HUD shall determine whether the IHA has satisfied, or has made reasonable progress towards satisfying, the applicable performance standards.

(b) *Notice of deficiency.* Based on HUD reviews of IHA performance and findings of any of the deficiencies in paragraph (d) of this section, HUD may issue to the IHA a notice of deficiency stating the specific program requirements that the IHA has violated and requesting the IHA to take any of the actions in paragraph (e) of this section.

(c) *Corrective action order.* (1) Based on HUD reviews of IHA performance and findings of any of the deficiencies paragraph (d) of this section, HUD may issue to the IHA a corrective action order, whether or not a notice of deficiency has previously been issued in regard to the specific deficiency on which the corrective action order is based. HUD may order corrective action at any time by notifying the IHA of the specific program requirements that the IHA has violated, and specifying that any of the corrective actions listed in paragraph (e) of this section shall be taken. HUD shall design corrective action to prevent a continuation of the deficiency, mitigate any adverse effects of the deficiency to the extent possible, or prevent a recurrence of the same or similar deficiencies.

(2) Before ordering corrective action, HUD will notify the IHA and give it an opportunity to consult with HUD regarding the proposed action.

(3) Any corrective action ordered by HUD shall become a condition of the grant agreement.

(4) If HUD orders corrective action by an IHA in accordance with this section, the IHA's Board of Commissioners shall notify affected residents of HUD's determination, the bases for the determination, the conditioning requirements imposed under paragraph (c) of this section, and the consequences to the IHA if it fails to comply with HUD's requirements.

(d) *Basis for corrective action.* HUD may order an IHA to take corrective action only if HUD determines:

(1) The IHA has not submitted a performance and evaluation report, in accordance with § 950.658;

(2) The IHA has not carried out its activities under the CGP program in a timely manner and in accordance with its Comprehensive Plan or HUD requirements, as described in paragraph (a)(1) of this section;

(3) The IHA does not have a continuing capacity to carry out its Comprehensive Plan in a timely manner or in accordance with its Comprehensive Plan or HUD requirements, as described in paragraph (a)(2) of this section;

(4) The IHA has not satisfied, or has not made reasonable progress towards satisfying, the performance standards described in paragraph (a)(3) of this section;

(5) An audit conducted in accordance with 24 CFR part 44 and § 950.120, or pursuant to other HUD reviews (including monitoring findings) reveals deficiencies that HUD reasonably believes require corrective action;

(6) The IHA has failed to repay HUD for amounts awarded under the CGP program that were improperly expended; or

(7) The IHA has been determined to be high risk, in accordance with § 950.135.

(e) *Types of corrective action.* HUD may direct an IHA to take one or more of the following corrective actions:

(1) Submit additional information:

(i) Concerning the IHA's administrative, planning, budgeting, accounting, management, and evaluation functions, to determine the cause for a IHA not meeting the standards in paragraphs (a)(1), (2), or (3) of this section;

(ii) Explaining any steps the IHA is taking to correct the deficiencies;

(iii) Documenting that IHA activities were not inconsistent with the IHA's annual statement or other applicable laws, regulations, or program requirements; and

(iv) Demonstrating that the IHA has a continuing capacity to carry out the Comprehensive Plan in a timely manner;

(2) Submit detailed schedules for completing the work identified in its Annual Statements and report periodically on its progress on meeting the schedules;

(3) Notwithstanding 24 CFR 85.36(g), submit to HUD the following documents for prior approval, which may include, but are not limited to:

(i) Proposed agreement with the architect/engineer (prior to execution);

(ii) Complete construction and bid documents (prior to soliciting bids);

(iii) Proposed award of contracts, including construction and equipment contracts and management contracts; or

(iv) Proposed contract modifications prior to issuance, including modifications to construction and equipment contracts, and management contracts.

(4) Submit additional material in support of one or more of the statements, resolutions, and certifications submitted as part of the IHA's Comprehensive Plan, Five-Year Action Plan, or Performance and Evaluation Report;

(5) Submit additional material in support of one or more of the statements, resolutions, and certifications submitted as part of the IHA's Comprehensive Plan, Five-Year Action Plan, or Performance and Evaluation Report;

(6) Reimburse, from non-HUD sources, one or more program accounts for any amounts improperly expended;

(7) Take such other corrective actions HUD determines appropriate to correct IHA deficiencies.

(8) Submit to an alternative management strategy which may involve third-party oversight or administration of the modernization function (see § 950.650); and

(9) Take such other corrective actions HUD determines appropriate to correct IHA deficiencies.

(f) *Failure to take corrective action.* In cases in which HUD has ordered corrective action and the IHA has failed to take the required actions within a reasonable time, as specified by HUD, HUD may take one or more of the following steps:

(1) Withhold some or all of the IHA's grant;

(2) Declare a breach of the ACC grant amendment with respect to some or all of the IHA's functions; or

(3) Any other sanction authorized by law or regulation.

(g) *Reallocation of funds that have been withheld.* If HUD has withheld for a prescribed period of time some or all of an IHA's annual grant, HUD may reallocate such amounts to other IHAs/ PHAs under the CGP program, subject to approval in appropriations acts. The reallocation shall be made to IHAs that HUD has determined to be administratively capable under § 950.135, and to PHAs under the CGP program that are not designated as either troubled or mod troubled under the PHMAP at 24 CFR part 901, based upon the relative needs of these IHAs and PHAs, as determined under the formula at § 950.604.

(h) *Right to appeal.* Before withholding some or all of the IHA's annual grant, declaring a breach of the ACC grant amendment, or reallocating funds that have been withheld, HUD

will notify the IHA and give it an opportunity, within a prescribed period of time, to present to ONAP Headquarters, in writing, any arguments or additional facts and data concerning the proposed action.

(i) *Notification of residents.* The IHA's Board of Commissioners shall notify affected residents of HUD's final determination to withhold funds, declare a breach of the ACC grant amendment, or reallocate funds, as well as the basis for, and the consequences resulting from, such a determination.

(j) *Recapture.* In addition, HUD may recapture for good cause any grant amounts previously provided to an IHA, based upon a determination that the IHA has failed to comply with the requirements of the CGP program. Before recapturing any grant amounts, HUD will notify the IHA and give it an opportunity to appeal in accordance with paragraph (h) of this section. Any reallocation of recaptured amounts will be in accordance with paragraph (g) of this section. The IHA's board of Commissioners shall notify affected residents of HUD's final determination to recapture any funds.

## **PART 965—PHA-OWNED OR LEASED PROJECTS—GENERAL PROVISIONS**

8. The heading for part 965 is revised to read as set forth above.

9. The authority citation for part 965 continues to read as follows:

Authority: 42 U.S.C. 1437, 1437a, 1437d, 1437g, and 3535(d). Subpart H is also issued under 42 U.S.C. 4821–4846.

### **Subpart A—Preemption of State Prevailing Wage Requirements**

10. The heading of subpart A is revised as set forth above.

#### **§ 965.101 [Amended]**

11. Section 965.101 is amended by:

a. Removing from the section heading the words, "With Respect to Maintenance and Operation of Projects";

b. Removing the parenthetical phrase "(including modernization)" from the introductory text of paragraph (a); and

c. Removing the words, "maintenance and operation" wherever they appear in paragraphs (a) introductory text, (a)(2), (b)(1) introductory text, (b)(2), and (b)(3), and adding in their place, the words, "development, maintenance, and modernization".

## **PART 968—PUBLIC HOUSING MODERNIZATION**

12. The authority citation for 24 CFR part 968 continues to read as follows:

Authority: 42 U.S.C. 1437d, 1437l, and 3535(d).

### Subpart A—General

13. Section 968.101 is amended by revising paragraph (a); removing the second sentence of paragraph (b)(2); revising paragraphs (b)(1), (b)(5), and (c); and adding a new paragraph (d), to read as follows:

#### § 968.101 Purpose and applicability.

(a) *Purpose.* The purpose of this part is to set forth the policies and procedures for the Modernization program authorizing HUD to provide financial assistance to Public Housing Agencies (PHAs).

(b) *Applicability.* (1) Subpart A of this part applies to all modernization under this part. Subpart B of this part sets forth the requirements and procedures for the Comprehensive Improvement Assistance Program (CIAP) for PHAs that own or operate fewer than 250 public housing units. Subpart C of this part sets forth the requirements and procedures for the Comprehensive Grant Program (CGP) for PHAs that own or operate 250 or more units. A PHA that qualifies for participation in the CGP is not eligible to participate in the CIAP. A PHA that has already qualified to participate in the CGP may elect to continue to participate in the CGP so long as it owns or operates at least 200 units.

(5) A development/building/unit which is assisted under section 5(j)(2) of the Act (Major Reconstruction of Obsolete Projects) (MROP) is eligible for section 14 funding (CIAP or CGP) where it received MROP funding after FFY 1988 and has reached Date of Full Availability (DOFA) or where it received MROP funding during FFYs 1986–1988 and all MROP funds have been expended.

(c) *Transition.* Any amount that HUD has approved for a PHA must be used for the purposes for which the funding was provided, or:

(1) For a CGP PHA, for purposes consistent with an approved Annual Statement or Five-Year Action Plan submitted by the PHA, as the PHA determines to be appropriate; or

(2) For a CIAP PHA, in accordance with a revised CIAP budget.

(d) *Approved information collections.* The following sections of this subpart have been approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 and assigned OMB approval number 2577-0044: §§ 968.135, 968.145, 968.210, 968.215, 968.225, and

968.230. The following sections of this subpart have been similarly approved and assigned approval number 2577.0157: §§ 968.310, 968.315, 968.325, and 968.330.

#### § 968.102 [Amended]

14. Section 968.102 is amended by removing the reference to “§ 968.310(d)” in paragraph (b) and adding in its place a reference to “§ 968.112(d)”.

15. Section 968.103 is amended by revising paragraphs (a), (b), (c), (e)(1) (i) and (ii) introductory text, (f)(1), (f)(2) introductory text, (f)(2)(i), (f)(2)(ii) (f), (g), and (h), and the heading to paragraph (e)(4), to read as follows:

#### § 968.103 Allocation of funds under section 14.

(a) *General.* This section describes the process for allocating modernization funds to the aggregate of PHAs and IHAs participating in the CIAP and to individual PHAs and IHAs participating in the CGP.

(b) *Set-aside for emergencies and disasters.* For each FFY, HUD shall reserve from amounts approved in the appropriation act for grants under this part and part 950 of this title, an amount not to exceed \$75 million (which shall include unused reserve amounts carried over from previous FFYs), which shall be made available to PHAs and IHAs for modernization needs resulting from natural and other disasters, and from emergencies. HUD shall replenish this reserve at the beginning of each FFY. Any unused funds from previous years may remain in the reserve until allocated. The requirements governing the reserve for disasters and emergencies and the procedures by which a PHA may request such funds, are set forth in § 968.104.

(c) *Set-aside for credits for mod troubled PHAs under subpart C of this part.* After deducting an amount for the reserve for natural and other disasters and for emergencies under paragraph (b) of this section, HUD shall set aside from the funds remaining no more than five percent for the purpose of providing credits to PHAs that were formerly designated as mod troubled agencies under the Public Housing Management Assessment Program (PHMAP) (see 24 CFR part 901). The purpose of this set-aside is to compensate these PHAs for amounts previously withheld by HUD because of a PHA's prior designation as a mod troubled agency. Since part 901 of this chapter does not apply to IHAs, they are not classified as “mod troubled” and they do not participate in

the set-aside credits established under paragraph (c) of this section.

\* \* \* \* \*

(e) \* \* \*

(1) \* \* \*

(i) *Statistically reliable data are available.* Where HUD determines that the data concerning the categories of backlog need identified under paragraph (e)(4) of this section are statistically reliable for individual IHAs and PHAs with 250 or more units, or for the aggregate of IHAs and PHAs with fewer than 250 units, which are not participating in the formula funding portion of the modernization program, it will base its allocation on direct estimates of the statutory categories of backlog need, based on the most recently available, statistically reliable data;

(ii) *Statistically reliable data are unavailable.* Where HUD determines that statistically reliable data concerning the categories of backlog need identified under paragraph (e)(4) of this section are not available for individual PHAs and IHAs with 250 or more units, it will base its allocation of funds under this section on estimates of the categories of backlog need using:

\* \* \* \* \*

(4) *Categories of backlog need.* \* \* \*

(f) \* \* \*

(1) *Statistically reliable data are available.* Where HUD determines that statistically reliable data are available concerning the categories of need identified under paragraph (f)(3) of this section for individual PHAs and IHAs with 250 or more units, and for the aggregate of PHAs and IHAs with fewer than 250 units, it shall base its allocation of assistance under this section on the needs that are estimated to have accrued since the date of the last objective measurement of backlog needs under paragraph (e)(1)(i) of this section;

(2) *Statistically reliable data are unavailable.* Where HUD determines that statistically reliable data concerning the categories of need identified under paragraph (f)(3) of this section are not available for individual PHAs and IHAs with 250 or more units, it shall base its allocation of assistance under this section on estimates of accrued need using:

(i) The most recently available data on the categories of accrual need under paragraph (f)(3) of this section;

(ii) \* \* \*

(F) The total number of units of each PHA or IHA that owns or operates 250 or more units. (weighted at .0144);

\* \* \* \* \*

(g) *Allocation of CIAP.* The formula amount determined under paragraphs

(e) and (f) of this section for PHAs and IHAs with fewer than 250 units shall be allocated to PHAs in accordance with the requirements of subpart B of this part (the CIAP), and to IHAs in accordance with the requirements of 24 CFR part 950, subpart I.

(h) *Allocation for CGP.* The formula amount determined under paragraphs (e) and (f) of this section for PHAs with 250 or more units shall be allocated in accordance with the requirements of subpart C of this part (the CGP), and for IHAs in accordance with the requirements of 24 CFR part 950, subpart I. A PHA that is eligible to receive a grant under the CGP may appeal the amount of its formula allocation in accordance with the requirements set forth in § 968.310(b). A PHA that is eligible to receive modernization funds under the CGP because it owns or operates 250 or more units is disqualified from receiving assistance under the CIAP under this part.

16. Section 968.105 is amended by adding in alphabetical order new definitions for “CGP”, “modernization program”, “modernization project”, and “reasonable cost”; by revising the definition “Force account labor”; removing the definition for “CIAP program”; and adding a definition for “CIAP” to read as follows:

**§ 968.105 Definitions.**

*CGP.* The Comprehensive Grant Program, which provides modernization funds on a formula basis to PHAs with 250 or more public housing units.

*CIAP.* The Comprehensive Improvement Assistance Program, which provides modernization funds on a competitive basis to PHAs with fewer than 250 public housing units.

*Force account labor.* Labor employed directly by the PHA on either a permanent or a temporary basis. See § 968.120.

*Modernization program.* A PHA’s program for carrying out modernization, as set forth in the approved CIAP budget or CGP Annual Statement.

*Modernization project.* The improvement of one or more existing public housing developments under a unique number designated for that modernization program. For each modernization project, HUD and the PHA shall enter into an ACC amendment, requiring low-income use of the housing for not less than 20 years from the date of the ACC amendment

(subject to sale of homeownership units in accordance with the terms of the ACC). The terms “modernization project number” and “comprehensive grant number” are used interchangeably.

*Reasonable cost.* Total unfunded hard cost needs for a development that do not exceed 90 percent of the computed Total Development Cost (TDC) for a new development with the same structure type and number and size of units in the market area.

**§ 968.312 [Redesignated as § 968.104]**

17. Section 968.312 is redesignated as § 968.104; and newly redesignated § 968.104 is amended by:

a. Removing from paragraph (a)(1) the phrase “under § 968.310(a)(3)”;

b. Removing references to “PHAs participating in CGP” and “PHAs participating in CIAP” in paragraphs (a)(1) and (a)(3), and adding in their place references to “CGP PHAs” and “CIAP PHAs”, respectively;

c. Removing references to “PHA participating in CGP” and “PHA participating in CIAP” in paragraph (a)(1), and adding in their place references to “CGP PHA” and “CIAP PHA”, respectively;

d. Adding a sentence at the end of paragraph (a)(3);

e. Removing from paragraphs (a)(1) and (b)(1) the two references to “§ 968.320” and adding in their place references to “§ 968.315”;

f. Amending paragraph (b)(1) in the fourth sentence, by adding after the words “insurance coverage” and before the period, the words “or other Federal assistance”; and in the fifth sentence, by adding before the word “PHA”, the word “CGP”; and

g. Amending paragraph (b)(3) by removing the phrase, “shall be in the form of a grant, and”; to read as follows:

**§ 968.104 Reserve for emergencies and disasters.**

(a) \* \* \*  
(3) \* \* \* A CIAP PHA is not required to repay assistance for its emergency needs from the reserve.

**§ 968.108 [Amended]**

18. Section 968.108 is amended by removing paragraph (f)(2) and redesignating paragraph (f)(3) as paragraph (f)(2).

**§ 968.110 [Amended]**

19. Section 968.110 is amended by removing and reserving paragraphs (i), (j), and (l), by removing from paragraph

(e)(3) the words “or tribal”, and by removing from paragraph (e)(3) the reference to “§ 968.120” and adding in its place a reference to “§ 965.101 of this chapter”.

20. A new § 968.112 is added, to read as follows:

**§ 968.112 Eligible costs.**

(a) *General.* A PHA may use financial assistance received under this part for the following eligible costs:

(1) For a CGP PHA, the eligible costs are:

(i) Undertaking activities described in its approved Annual Statement under § 968.325 and approved Five-Year Action Plan under § 968.315(e)(5);

(ii) Carrying out emergency work, whether or not the need is indicated in the PHA’s approved Comprehensive Plan, including Five-Year Action Plan, or Annual Statement;

(iii) Funding a replacement reserve to carry out eligible activities in future years, subject to the restrictions set forth in paragraph (f) of this section;

(iv) Preparing the Comprehensive Plan and Five-Year Action Plan under § 968.315 and the Annual Submission under § 968.325, including reasonable costs necessary to assist residents to participate in a meaningful way in the planning, implementation and monitoring process; and

(v) Carrying out an audit, in accordance with 24 CFR part 44.

(2) For a CIAP PHA, the eligible costs are activities approved by HUD and included in an approved CIAP budget.

(b) *Demonstration of viability.* Except in the case of emergency work, a PHA shall only expend funds on a development for which the PHA has determined, and HUD agrees, that the completion of the improvements and replacements (for CGP PHAs, as identified in the Comprehensive Plan) will reasonably ensure the long-term physical and social viability of the development at a reasonable cost (as defined in § 968.105), or for essential non-routine maintenance needed to keep the property habitable until the demolition or disposition application is approved and residents are relocated.

(c) *Physical improvements.* Eligible costs include alterations, betterments, additions, replacements, and non-routine maintenance that are necessary to meet the modernization and energy conservation standards prescribed in § 968.115. These mandatory standards may be exceeded when a PHA (and HUD in the case of CIAP PHAs) determines that it is necessary or highly desirable for the long-term physical and social viability of the individual development. Development specific



work includes work items that are modest in design and cost, but still blend in with the design and architecture of the surrounding community by including amenities, quality materials and design and landscaping features that are customary for the locality and culture. The Field Office has the authority to approve nondwelling space where such space is needed to administer, and is of direct benefit to, the public housing program. If demolition or disposition is proposed, a PHA shall comply with 24 CFR part 970. Additional dwelling space may be added to existing units.

(d) *Turnkey III developments.* (1) *General.* Eligible physical improvement costs for existing Turnkey III developments are limited to work items that are not the responsibility of the homebuyer families and that are related to health and safety, correction of development deficiencies, physical accessibility, energy audits and cost-effective energy conservation measures, or LBP testing, interim containment, professional risk assessment and abatement. In addition, management improvements are eligible costs.

(2) *Ineligible costs.* Routine maintenance or replacements, and items that are the responsibility of the homebuyer families are ineligible costs.

(3) *Exception for vacant or non-homebuyer-occupied Turnkey III units.*

(i) Notwithstanding the requirements of paragraph (d)(1) of this section, a PHA may substantially rehabilitate a Turnkey III unit whenever the unit becomes vacant or is occupied by a non-homebuyer family in order to return the unit to the inventory or make the unit suitable for homeownership purposes. A PHA that intends to use funds under this paragraph must identify in its CIAP application or CGP annual submission the estimated number of units proposed for substantial rehabilitation and subsequent sale. In addition, a PHA must demonstrate, for each of the Turnkey III units proposed to be substantially rehabilitated, that it has homebuyers who both are eligible for homeownership, in accordance with the requirements of 24 CFR part 904, and have demonstrated their intent to be placed into the unit.

(ii) Before a PHA may be approved for substantial rehabilitation of a unit under this paragraph, it must first deplete any Earned Home Payments Account (EHPA) or Non-Routine Maintenance Reserve (NRMR) pertaining to the unit, and request the maximum amount of operating subsidy. Any increase in the value of a unit caused by its substantial rehabilitation under this paragraph shall be reflected solely by its subsequent

appraised value, and by an automatic increase in its selling price.

(e) *Demolition and conversion costs.* Eligible costs include:

(1) Demolition of dwelling units or non-dwelling facilities, where the demolition is approved by HUD under 24 CFR part 970, and related costs, such as clearing and grading the site after demolition and subsequent site improvement to benefit the remaining portion of the existing development; and

(2) Conversion of existing dwelling units to different bedroom sizes or to non-dwelling use.

(f) *Replacement reserve costs* (for CGP only). (1) Funding a replacement reserve to carry out eligible activities in future years is an eligible cost, subject to the following restrictions:

(i) Annual CGP funds are not needed for existing needs, as identified by the PHA in its needs assessments; or

(ii) A physical improvement requires more funds than the PHA would receive under its annual formula allocation; or

(iii) A management improvement requires more funds than the PHA may use under its 20% limit for management improvements (except as provided in paragraph (n)(2)(i) of this section), and the PHA needs to save a portion of its annual grant, in order to combine it with a portion of subsequent year(s) grants to fund the work item.

(2) The PHA shall invest replacement reserve funds so as to generate a return equal to or greater than the average 91-day Treasury bill rate.

(3) Interest earned on funds in the replacement reserve will not be added to the PHA's income in the determination of a PHA's operating subsidy eligibility, but must be used for eligible modernization costs.

(4) To the extent that its annual formula allocation and any unobligated balances of modernization funds are not adequate to meet emergency needs, a PHA must first use its replacement reserve, where funded, to meet emergency needs, before requesting funds from the reserve under § 968.104.

(5) A PHA is not required to use its replacement reserve for costs related to natural and other disasters.

(g) *Management improvement costs.*

(1) *General.* Management improvements that are development-specific or PHA-wide in nature are eligible costs where needed to upgrade the operation of the PHA's developments, sustain physical improvements at those developments or correct management deficiencies. A PHA's ongoing operating expenses are ineligible management improvement costs. For CIAP PHAs, management

improvements may be funded as a single work item.

(2) *Eligible costs.* Eligible costs include:

(i) *General management improvement costs.* Eligible costs include general management improvement costs, such as: management, financial, and accounting control systems of the PHA; adequacy and qualifications of PHA personnel, including training; resident programs and services through the coordination of the provision of social services from tribal or local government or other public and private entities; resident and development security; resident selection and eviction; occupancy; rent collection; maintenance; and equal opportunity.

(ii) *Economic development costs.* Eligible costs include job training for residents and resident business development activities, for the purpose of carrying out activities related to the modernization-funded management and physical improvements. HUD encourages PHAs, to the greatest extent feasible, to hire residents as trainees, apprentices, or employees to carry out the modernization program under this part, and to contract with resident-owned businesses for modernization work.

(iii) *Resident management costs.* Eligible costs include technical assistance to a resident council or resident management corporation (RMC), as defined in part 964, in order to: determine the feasibility of resident management to carry out management functions for a specific development or developments; train residents in skills directly related to the operations and management of the development(s) for potential employment by the RMC; train RMC board members in community organization, board development, and leadership; and assist in the formation of an RMC.

(iv) *Resident homeownership costs.* Eligible costs are limited to the study of the feasibility of converting rental to homeownership units and the preparation of an application for conversion to homeownership or sale of units.

(v) *Preventive maintenance system.* Eligible costs include the establishment of a preventive maintenance system or improvement of an existing system. A preventive maintenance system must provide for regular inspections of building structures, systems and units and distinguish between work eligible for operating funds (routine maintenance) and work eligible for modernization funding (non-routine maintenance).



(h) *Drug elimination costs.* Eligible costs include drug elimination activities involving management or physical improvements, as specified by HUD.

(i) *LBP costs.* Eligible costs include professional risk assessments and interim containment of family developments/buildings constructed before 1980, testing and abatement of family developments/buildings constructed before 1978, and costs for insurance coverage for pollution hazards associated with the testing, abatement, clean-up and disposal of LBP on applicable surfaces of family developments/buildings constructed before 1978.

(j) *Administrative costs.* Administrative costs necessary for the planning, design, implementation and monitoring of the physical and management improvements are eligible costs and include the following:

(1) *Salaries.* The salaries of non-technical and technical PHA personnel assigned full-time or part-time to modernization are eligible costs only where the scope and volume of the work are beyond that which could be reasonably expected to be accomplished by such personnel in the performance of their non-modernization duties. A PHA shall properly apportion to the appropriate program budget any direct charges for the salaries of assigned full- or part-time staff (e.g., to the CIAP, CGP or operating budget);

(2) *Employee benefit contributions.* PHA contributions to employee benefit plans on behalf of non-technical and technical PHA personnel are eligible costs in direct proportion to the amount of salary charged to the CIAP or CGP, as appropriate;

(3) *Preparation of CIAP or CGP required documents;*

(4) *Resident participation.* Eligible costs include those associated with ensuring the meaningful participation of residents in the development of the CIAP Application or the CGP Annual Submission and Comprehensive Plan and the implementation and monitoring of the approved modernization program; and

(5) *Other administrative costs,* such as telephone and facsimile, as specified by HUD.

(k) *Audit costs (CGP only).* Eligible costs are limited to the portion of the audit costs that are attributable to the modernization program.

(l) *Architectural/engineering and consultant fees.* Eligible costs include fees for planning, identification of needs, detailed design work, preparation of construction and bid documents and other required documents, LBP professional risk

assessments and testing, and inspection of work in progress.

(m) *Relocation costs.* Eligible costs include relocation and other assistance for permanent and temporary relocation, as a direct result of rehabilitation, demolition or acquisition for a modernization-funded activity, where this assistance is required by 49 CFR part 24 or § 968.108.

(n) *Cost limitations.* (1) *CIAP costs.* (i) *Management improvement costs.* Management improvement costs shall not exceed a percentage of the CIAP funds available to a Field Office in a particular FFY, as specified by HUD.

(ii) *Planning costs.* Planning costs are costs incurred before HUD approval of the CIAP application and which are related to developing the CIAP application or carrying out eligible modernization planning, such as detailed design work, preparation of solicitations, and LBP professional risk assessment and testing. Planning costs may be funded as a single work item. If a PHA incurs planning costs without prior HUD approval, a PHA does so with the full understanding that the costs may not be reimbursed upon approval of the CIAP application. Planning costs shall not exceed 5 percent of the CIAP funds available to a Field Office in a particular FFY.

(2) *CGP costs.* (i) *Management improvement costs.* Notwithstanding the full fungibility of work items, a PHA shall not use more than a total of 20 percent of its annual grant for management improvement costs in account 1408, unless specifically approved by HUD or the PHA has been designated as both an over-all high performer and mod-high performer under the PHMAP.

(ii) *Administrative costs.* Notwithstanding the full fungibility of work items, a PHA shall not use more than a total of 10 percent of its annual grant on administrative costs in account 1410, excluding any costs related to lead-based paint or asbestos testing (whether conducted by force account employees or by a contractor), in-house architectural/engineering (A/E) work, or other special administrative costs required by State or local law, unless specifically approved by HUD.

(3) *Program benefit.* Where the physical or management improvement, including administrative cost, will benefit programs other than Public Housing, such as Section 8 or local revitalization programs, eligible costs are limited to the amount directly attributable to the public housing program.

(4) *No duplication.* Any eligible cost for an activity funded by CIAP or CGP

shall not also be funded by any other HUD program.

(o) *Ineligible costs.* Ineligible costs include:

(1) Luxury improvements;

(2) Indirect administrative costs (overhead), as defined in OMB Circular A-87;

(3) Public housing operating assistance;

(4) Direct provision of social services, through either force account or contract labor, from FFY 1996 and future FFYs funds, unless otherwise provided by law; and

(5) Other ineligible activities, as specified by HUD.

(p) *Expanded eligibility for FFY 1995 and prior year modernization funds.* The FFY 1995 Rescissions Act expanded the eligible activities that may be funded with CIAP or CGP assistance provided from FFY 1995 and prior FFY funds. Such activities include, but are not limited to:

(1) New construction or acquisition of additional public housing units, including replacement units;

(2) Modernization activities related to the public housing portion of housing developments held in partnership, or cooperation with non-public housing entities; and

(3) Other activities related to public housing, including activities eligible under the Urban Revitalization Demonstration (HOPE VI).

21. Section 968.115 is revised to read as follows:

**§ 968.115 Modernization and energy conservation standards.**

All improvements funded under this part shall:

(a) Meet the modernization standards as prescribed by HUD;

(b) Incorporate cost-effective energy conservation measures, identified in the PHA's most recently updated energy audit, conducted pursuant to part 965, subpart C;

(c) Where changing or installing a new utility system, conduct a life-cycle cost analysis, reflecting installation and operating costs; and

(d) Provide decent, safe, and sanitary living conditions in PHA-owned and PHA-operated public housing.

22. Section 968.120 is revised to read as follows:

**§ 968.120 Force account.**

(a) For both CIAP and CGP, a PHA may undertake the activities using force account labor, only where specifically approved by HUD in the CIAP budget or CGP Annual Statement, except no prior HUD approval is required where the PHA is designated as both an overall

high performer and Modernization high performer under the PHMAP.

(b) If the entirety of modernization activity (including the planning and architectural design of the rehabilitation) is administered by the RMC, the PHA shall not retain for any administrative or other reason, any portion of the modernization funds provided, unless the PHA and the RMC provide otherwise by contract.

23. New §§ 968.125, 968.130, and 968.135 are added, to read as follows:

**§ 968.125 Initiation of modernization activities.**

After HUD has approved the modernization program and entered into an ACC amendment with the PHA, a PHA shall undertake the modernization activities and expenditures set forth in its approved CIAP budget or CGP Annual Statement/Five-Year Action Plan in a timely, efficient and economical manner. All approved funding must be obligated within two years of approval and expended within three years of approval unless HUD approves a longer time period in the PHA's implementation schedule, as set forth in the CIAP budget or CGP Annual Statement. HUD may approve a longer time period for such reasons as the large size of the grant or the complexity of the work.

**§ 968.130 Fund requisitions.**

To draw down modernization funds against the approved CIAP budget or CGP Annual Statement, a PHA shall comply with requirements prescribed by HUD.

**§ 968.135 Contracting requirements.**

In addition to the requirements specified in 24 CFR parts 5, 85, and 965, subpart A, and § 968.110(e), the following provisions apply:

(a) *Architect/engineer and other professional services contracts.* For CIAP only and notwithstanding 24 CFR 85.36(g), a PHA shall comply with the following HUD requirements:

(1) Where the proposed contract amount exceeds the HUD-established threshold, submit the contract for prior HUD approval before execution or issuance; or

(2) Where the proposed contract amount does not exceed the HUD-established threshold, certify that the scope of work is consistent with the originally approved modernization program, and that the amount is appropriate and does not result in the total HUD-approved CIAP budget being exceeded.

(b) *Assurance of completion.* For both CIAP and CGP and notwithstanding 24

CFR 85.36(h), for each construction contract over \$100,000, the contractor shall furnish a bid guarantee from each bidder equivalent to 5% of the bid price; and one of the following:

(1) A performance and payment bond for 100 percent of the contract price; or

(2) Separate performance and payment bonds, each for 50% or more of the contract price; or

(3) A 20% cash escrow; or

(4) a 25% irrevocable letter of credit.

(c) *Construction solicitations.* For CIAP only and notwithstanding 24 CFR 85.36(g), a PHA shall comply with HUD requirements to either:

(1) Where the estimated contract amount exceeds the HUD-established threshold, submit a complete construction solicitation for prior HUD approval before issuance; or

(2) Where the estimated contract amount does not exceed the HUD-established threshold, certify receipt of the required architect's/engineer's certification that the construction documents accurately reflect HUD-approved work and meet the modernization and energy conservation standards and that the construction solicitation is complete and includes all mandatory items.

(d) *Contract awards.* (1) For CIAP only, a PHA shall obtain HUD approval of the proposed award of a contract if the contract work is inconsistent with the originally approved modernization program or the procurement meets the criteria set forth in 24 CFR 85.36(g)(2)(i) through (iv). In all other instances, a PHA shall make the award without HUD approval after the PHA has certified that:

(i) The solicitation and award procedures were conducted in compliance with State or local laws and Federal requirements;

(ii) The award does not meet the criteria in 24 CFR 85.36(g)(2)(i) through (iv) for prior HUD approval; and

(iii) The contractor is not on the Lists of Parties Excluded from Federal Procurement or Nonprocurement Programs;

(2) For CGP only, a PHA shall obtain HUD approval of the proposed award of a contract if the procurement meets the criteria set forth in 24 CFR 85.36(g)(2)(i) through (iv).

(e) *Contract modifications.* For CIAP only and notwithstanding 24 CFR 85.36(g), except in an emergency endangering life or property, a PHA shall comply with HUD requirements to either:

(1) Where the proposed contract modification exceeds the HUD-established threshold, submit the

proposed modification for prior HUD approval before issuance; or

(2) Where the proposed contract modification does not exceed the HUD-established threshold, certify that the proposed modification is within the scope of the contract and that any additional costs are within the total HUD-approved CIAP budget amount.

(f) *Construction requirements.* Where indicated by poor performance, a PHA may be required to submit to HUD periodic progress reports and, for prior HUD approval, construction completion documents above a HUD-specified amount. For CGP only, a PHA is notified of additional construction requirements by a notice of deficiency or a corrective action order.

(g) *Reward for high performers.* For CIAP only, if a PHA is both an overall high performer and a modernization high performer under the Public Housing Management Assessment Program (PHMAP), HUD will not establish thresholds, and the PHA is not required to obtain prior HUD approval, under paragraphs (a), (c), and (e) of this section.

**§ 968.240 [Redesignated as § 968.140]**

24. Section 968.240 is redesignated as § 968.140.

25. A new § 968.145 is added to subpart A, to read as follows:

**§ 968.145 Fiscal closeout.**

(a) *Actual modernization cost certificate (AMCC).* Upon expenditure by the PHA of all funds, or termination by HUD of the activities funded in a modernization program, a PHA shall submit the AMCC, in a form prescribed by HUD, to HUD for review and approval for audit. After audit verification, HUD shall approve the AMCC.

(b) *Audit.* The audit shall follow the guidelines prescribed in 24 CFR part 44, Non-Federal Government Audit Requirements. If the pre-audit or post-audit AMCC indicates that there are excess funds, a PHA shall immediately remit the excess funds as directed by HUD. If the pre-audit or post-audit AMCC discloses unauthorized or ineligible expenditures, a PHA shall immediately take such corrective actions as HUD may direct.

26. Subpart B is revised to read as follows:

**Subpart B—Comprehensive Improvement Assistance Program (For PHAs That Own or Operate Fewer Than 250 Units)**

968.205 Definitions.

968.210 Procedures for obtaining approval of a modernization program.

968.215 Resident and homebuyer participation.

- 968.225 Budget revisions.
- 968.230 Progress reports.
- 968.235 Time extensions.
- 968.240 HUD review of PHA performance.

**Subpart B—Comprehensive Improvement Assistance Program (For PHAs That Own or Operate Fewer Than 250 Units)**

**§ 968.205 Definitions.**

In addition to the definitions in § 968.105, the following definitions apply to this subpart:

*Emergency Modernization (CIAP).* A type of modernization program for a development that is limited to physical work items of an emergency nature that poses an immediate threat to the health or safety of residents or is related to fire safety, and that must be corrected within one year of CIAP funding approval.

*Management capability.* A PHA has management capability if it is:

(1) Not designated as Troubled under part 901 of this chapter, Public Housing Management Assessment Program (PHMAP); or

(2) Designated as Troubled, but has a reasonable prospect of acquiring management capability through CIAP-funded management improvements and administrative support. A Troubled PHA is eligible for Emergency Modernization only, unless it is making reasonable progress toward meeting the performance targets established in its memorandum of agreement or equivalent under § 901.140 of this chapter or has obtained alternative oversight of its management functions.

*Modernization capability.* A PHA has modernization capability if it is:

(1) Not designated as Modernization Troubled under part 901 of this chapter, PHMAP; or

(2) Designated as Modernization Troubled, but has a reasonable prospect of acquiring modernization capability through CIAP-funded management improvements and administrative support, such as hiring staff or contracting for assistance. A Modernization Troubled PHA is eligible for Emergency Modernization only, unless it is making reasonable progress toward meeting the performance targets established in its memorandum of agreement or equivalent under § 901.140 of this chapter or has obtained alternative oversight of its modernization functions. Where a PHA does not have a funded modernization program in progress, the Field Office shall determine whether the PHA has a reasonable prospect of acquiring modernization capability through hiring staff or contracting for assistance.

*Other Modernization (modernization other than emergency).* A type of modernization program for a development that includes one or more physical work items, where HUD determines that the physical improvements are necessary and sufficient to extend substantially the useful life of the development, and/or one or more development specific or PHA-wide management work items (including planning costs), and/or lead-based paint testing, professional risk assessments, interim containment, and abatement.

*Work item.* Any separately identifiable unit of work constituting a part of a modernization program.

**§ 968.210 Procedures for obtaining approval of a modernization program.**

(a) *HUD notification.* After modernization funds for a particular FFY become available, HUD shall publish in the Federal Register a notice of funding availability (NOFA), the time frame for submission of the CIAP Application, and other pertinent information.

(b) *PHA consultation with local officials and residents/homebuyers.* A PHA shall develop the application in consultation with local officials and residents/homebuyers, as set forth in § 968.215.

(c) *PHA application.* A PHA shall submit to HUD an application, in a form prescribed by HUD. Where a PHA has not included some of its developments in the CIAP application, HUD may not consider funding any non-emergency work at excluded developments or subsequently approve use of leftover funds at excluded developments.

(d) *Completeness Review.* To be eligible for processing, an application must be physically received by HUD by the time and date specified in the NOFA. Immediately after the application deadline, HUD shall perform a completeness review to determine whether the application is complete, responsive to the NOFA, and acceptable for technical processing.

(1) If the application form or any other essential document, as specified in the NOFA, is missing, the PHA's application will be considered substantially incomplete and, therefore, ineligible for further processing. HUD shall immediately notify the PHA in writing.

(2) If other required documents, including certifications, as specified in the NOFA, are missing or there is a technical mistake, such as no signature on a submitted form, HUD shall immediately notify the PHA in writing to submit or correct the deficiency

within a specified period of time from the date of HUD's written notification. This is not additional time to substantially revise the application. Deficiencies which may be corrected at this time are inadvertently omitted documents or clarifications of previously submitted material and other changes which are not of such a nature as to improve the competitive position of the application.

(3) If a PHA fails to submit or correct the items within the required time period, the PHA's application will be ineligible for further processing. HUD shall immediately notify the PHA in writing after this occurs.

(4) A PHA may submit an application for Emergency Modernization whenever needed.

(e) *Eligibility Review.* (1) *Eligibility for processing.* To be eligible for processing:

(i) Each eligible development for which work is proposed has reached the Date of Full Availability (DOFA) and is under ACC at the time of CIAP application submission; and

(ii) Where funded under Major Reconstruction of Obsolete Projects (MROP) after FFY 1988, the development/building/unit has reached DOFA or, where funded during FFYs 1986–1988, all MROP funds for the development/building have been expended.

(2) *Eligibility for processing on reduced scope.* When the following conditions exist, a PHA will be reviewed on a reduced scope:

(i) *Section 504 compliance.* Where a PHA has not completed all required structural changes to meet the need for accessible units, as identified in the PHA's Section 504 needs assessment, the PHA is eligible for processing only for Emergency Modernization or physical work needed to meet Section 504 requirements.

(ii) *Lead-based paint (LBP) testing compliance.* Where a PHA has not complied with the statutory requirement to complete LBP testing on all pre-1978 family units, the PHA is eligible for processing only for Emergency Modernization or work needed to complete the testing.

(iii) *Fair Housing and Equal Opportunity (FHEO) compliance.* Where a PHA has not complied with FHEO requirements set forth in § 968.110, as evidenced by an enforcement action, finding or determination, the PHA is eligible for processing only for Emergency Modernization or for work needed to remedy the civil rights deficiencies—unless the PHA is implementing a voluntary compliance agreement or settlement agreement designed to correct the area(s) of

noncompliance. The enforcement actions, findings, or determinations that trigger limited eligibility are described in paragraphs (e)(2)(iii) (A) through (E) of this section:

(A) A pending proceeding against the PHA based upon a charge of discrimination issued under the Fair Housing Act. A charge of discrimination is a charge under section 810(g)(2) of the Fair Housing Act (42 U.S.C. 3610(g)(2)), issued by the Department's General Counsel or legally authorized designee;

(B) A pending civil rights suit against the PHA, referred by the Department's General Counsel and instituted by the Department of Justice;

(C) Outstanding HUD findings of PHA noncompliance with civil rights statutes and executive orders specified in 24 CFR part 5 and § 968.110 or implementing regulations, as a result of formal administrative proceedings;

(D) A deferral of the processing of applications from the PHA imposed by HUD under Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d-1) and HUD implementing regulations (24 CFR 1.8), the Attorney General's Guidelines (28 CFR 50.3), and procedures (HUD Handbook 8040.1), or under Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and HUD implementing regulations (24 CFR 8.57); or

(E) An adjudication of a violation under any of the civil rights authorities specified in 24 CFR part 5 and § 968.110 in a civil action filed against the PHA by a private individual.

(f) *Technical processing.* After all CIAP applications are reviewed for eligibility, HUD shall categorize the eligible PHAs and their developments into two processing groups: Group 1 for Emergency Modernization; and Group 2 for Other Modernization. PHA developments may be included in both groups and the same development may be in each group. However, a PHA is only required to submit one CIAP application. Group 1 developments are not subject to the technical review rating and ranking and the long-term viability and reasonable cost determination. Group 2 developments are subject to the technical review rating and ranking and the long-term viability and reasonable cost determination. Preference will be given to PHAs which request assistance for developments having conditions which threaten the health or safety of the residents or having a significant number of vacant, substandard units, and which have demonstrated a capability of carrying out the proposed activities.

(g) *Rating on technical review factors.* After categorizing the eligible PHAs/developments into Group 1 and Group

2, HUD shall review and rate each Group 2 PHA on each of the following technical review factors:

(1) Extent and urgency of need, including need to comply with statutory, regulatory or court-ordered deadlines;

(2) Extent of vacancies, where the vacancies are not due to insufficient demand;

(3) PHA's modernization capability;

(4) PHA's management capability;

(5) Degree of resident involvement in PHA operations;

(6) Degree of PHA activity in resident initiatives, including resident management, economic development, and drug elimination efforts;

(7) Degree of resident employment;

(8) Local government support for proposed modernization; and

(9) Such additional factors as the Secretary determines necessary and appropriate.

(h) *Ranking and selection for Joint Review.* After rating all Group 2 PHAs/developments, HUD shall then rank each Group 2 PHA based on its total score, list Group 2 PHAs in descending order, subject to confirmation of need and cost at Joint Review, and identify for Joint Review selection the highest PHA ranking applications in Group 2 and other Group 2 PHAs with lower ranking applications, but with high priority needs, which most reasonably approximate the amount of modernization which can be funded. High priority needs are non-emergency needs, but related to: health or safety; vacant, substandard units; structural or system integrity; or compliance with statutory, regulatory or court-ordered deadlines. All Group 1 applications are automatically selected for Joint Review.

(i) *Joint Review.* The purpose of Joint Review is for HUD to discuss with a PHA the proposed modernization program, as set forth in the CIAP Application, review long-term viability and cost reasonableness determinations, and determine the size of the grant, if any, to be awarded. HUD shall notify each PHA whose application has been selected for further processing as to whether Joint Review will be conducted on-site or off-site (e.g., by telephone or in-office meeting). A PHA shall prepare for Joint Review by preparing a draft CIAP budget and reviewing the other items to be covered during Joint Review, as prescribed by HUD. If conducted on-site, Joint Review may include an inspection of the proposed physical work. PHAs not selected for Joint Review will be advised in writing of the reasons for non-selection.

(j) *Funding decisions.* After all Joint Reviews are completed, HUD shall

adjust the PHAs, developments, and work items to be funded and the amounts to be awarded, on the basis of information obtained from Joint Reviews, environmental reviews, and FHEO review, and make the funding decisions. A PHA will not be selected for CIAP funding if there is a duplication of funding. HUD shall select all bona fide emergencies in Group 1 before funding Group 2 applications. After funding announcement, HUD shall request a funded PHA to submit a CIAP budget, including an implementation schedule, and any other required documents, including the ACC amendment. PHAs not selected for funding will be advised in writing of the reasons for non-selection.

(k) *ACC amendment.* After HUD approval of the CIAP budget, HUD and the PHA shall enter into an ACC amendment in order for the PHA to draw down modernization funds. The ACC amendment shall require low-income use of the housing for not less than 20 years from the date of the ACC amendment (subject to sale of homeownership units in accordance with the terms of the ACC). The PHA Executive Director, where authorized by the Board of Commissioners and permitted by State law, may sign the ACC amendment on behalf of the PHA. HUD has the authority to condition an ACC amendment (e.g., to require a PHA to hire a modernization coordinator or contract administrator to administer its modernization program).

(l) *Declaration of trust.* As HUD may require, the PHA shall execute and file for record a Declaration of Trust, as provided under the ACC, to protect the rights and interests of HUD throughout the 20-year period during which the PHA is obligated to operate its developments in accordance with the ACC, the Act, and HUD regulations and requirements.

#### **§ 968.215 Resident and homebuyer participation.**

A PHA shall establish a Partnership Process, as defined in § 968.105, to develop, implement and monitor the CIAP. Before submission of the CIAP application, a PHA shall consult with the residents, the resident organization, or the resident management corporation (see part 964, subpart C of this chapter) (herein referred to as the resident) of the development(s) being proposed for modernization, regarding its intent to submit an application and to solicit resident comments. A PHA shall give residents a reasonable opportunity to present their views on the proposed modernization and alternatives to it and shall give full and serious consideration

to resident recommendations. A PHA shall respond in writing to the residents, indicating its acceptance or rejection of resident recommendations, consistent with HUD requirements and the PHA's own determination of efficiency, economy, and need. After HUD approval of the modernization program, a PHA shall inform the residents of the approved work items and its progress during implementation. Where HUD does not approve the modernization program, a PHA shall so inform the residents.

#### **§ 968.225 Budget revisions.**

(a) A PHA shall not incur any modernization cost in excess of the total HUD-approved CIAP budget. A PHA shall submit a budget revision, in a form prescribed by HUD, if the PHA plans to deviate from the originally approved modernization program, as it was competitively funded, by deleting or substantially revising approved work items or adding new work items that are unrelated to the originally approved modernization program, or to change the method of accomplishment from contract to force account labor, except as provided in paragraph (b)(4) of this section.

(b) In addition to the requirements of paragraph (a) of this section, a PHA shall comply with the following requirements:

(1) A PHA is not required to obtain prior HUD approval if, in order to complete the originally approved modernization program, the PHA needs to delete or revise approved work items or add new related work items consistent with the original modernization program. In such case, a PHA shall certify that the revisions are necessary to carry out the approved work and do not result in substantial changes to the competitively funded modernization program.

(2) A PHA shall not incur any modernization cost on behalf of any development that is not covered by the original CIAP application.

(3) Where there are funds leftover after completion of the originally approved modernization program, a PHA may, without prior HUD approval, use the remaining funds to carry out eligible modernization activities at developments covered by the original CIAP application.

(4) If a PHA is both an overall high performer and a modernization high performer under the Public Housing Management Assessment Program (PHMAP), the PHA is not required to obtain prior HUD approval to change the method of accomplishment from contract to force account labor.

#### **§ 968.230 Progress reports.**

For each six-month period ending March 31 and September 30, until completion of the modernization program or expenditure of all funds, a PHA shall submit to HUD a progress report, in a form prescribed by HUD. Where HUD determines that a PHA is having implementation problems, HUD may require more frequent reporting.

#### **§ 968.235 Time extensions.**

A PHA shall not obligate or expend funds after the obligation or expenditure deadline date approved by HUD in the original implementation schedule without a time extension, as follows:

(a) *Certification.* A PHA may extend an obligation or expenditure deadline date no later than 30 calendar days after the existing deadline date, without prior HUD approval, for a period commensurate with the delay, where the PHA certifies that the delay is due to reasons outside of the PHA's control, such as:

(1) Need to use leftover funds from a completed modernization program for additional work;

(2) Unforeseen delays in contracting or contract administration;

(3) Litigation; and

(4) Delay by HUD or other institutions. Delay by the PHA's staff or Board of Commissioners or a change in the Executive Director is not considered to be outside of the PHA's control.

(b) *Prior HUD approval.* Where a PHA is unable to meet an obligation or expenditure deadline date and the delay is due to reasons within the PHA's control, the PHA may request HUD approval of a time extension no later than 30 calendar days after the deadline date, to avoid recapture of funds. The request shall include an explanation of the delay, steps taken to prevent future delay, and the requested extension.

#### **§ 968.240 HUD review of PHA performance.**

HUD shall periodically review PHA performance in carrying out its approved modernization program to determine compliance with HUD requirements, the adequacy of a PHA's inspections as evidenced by the quality of work, and the timeliness of the work. HUD's review may be conducted either in-office or on-site. Where conducted in-office, a PHA shall forward any requested documents to HUD for post-review. Where deficiencies are noted, a PHA shall take such corrective actions as HUD may direct.

27. The heading for subpart C is revised to read as follows:

### **Subpart C—Comprehensive Grant Program (for PHAs That Own or Operate 250 or More Public Housing Units)**

#### **§ 968.301 [Removed]**

28. Section 968.301 is removed.

#### **§ 968.305 [Amended]**

29. Section 968.305 is amended by:

- Removing the definition for “*comprehensive grant number*”; and
- Removing references to “§ 968.310(a)(3)”, “968.320(d)(5)”, and “968.320(d)”, wherever they appear, and adding in their place, respectively, references to “968.112(f)”, “968.315(e)(5)”, and “968.315(e)”.

#### **§ 968.310 [Removed]**

30. Section 968.310 is removed.

#### **§ 968.315 [Redesignated as § 968.310]**

31. Section 968.315 is redesignated as § 968.310; and newly redesignated § 968.310 is amended by:

a. Removing from paragraph (a)(1) the phrase, “under this subpart,”;

b. Removing from paragraph (b)(1) the references to “968.320” and “968.330” and adding in their place references to “968.315” and “968.325”, respectively;

c. Removing from paragraph (c)(5) the references to “part 905” and “§ 905.135” and adding in their place references to “part 950” and “§ 950.135”, respectively;

d. Removing paragraph (d); and

e. Revising the section heading to read, “*§ 968.310 Determination of formula amount.*”

32. A new § 968.315 is added, to read as follows:

#### **§ 968.315 Comprehensive Plan (including Five-Year Action Plan).**

(a) *Submission.* As soon as possible after modernization funds first become available for allocation under this subpart, HUD shall notify PHAs in writing of their formula amount. For planning purposes, PHAs may use the amount they received under CGP in the prior year in developing their comprehensive plan, or they may wait for the annual HUD notification of formula amount under § 968.310(b)(1).

(b)(1) *Resident participation.* A PHA is required to develop, implement, monitor and annually amend portions of its comprehensive plan in consultation with residents of the developments covered by the comprehensive plan. In addition, the PHA shall consult with resident management corporations (RMCs) to the extent that an RMC manages a development covered by the comprehensive plan. The PHA, in partnership with the residents, must develop and implement a process for

resident participation that ensures that residents are involved in a meaningful way in all phases of the CGP. Such involvement shall involve implementing the Partnership Process as a critical element of the CGP.

(2) *Establishment of Partnership Process.* The PHA, in partnership with the residents of the developments covered by the plan (and which may include resident leaders, resident councils, resident advisory councils/boards, and RMCs) must establish a Partnership Process to develop and implement the goals, needs, strategies and priorities identified in the comprehensive plan. After residents have organized to participate in the CGP, they may decide to establish a volunteer advisory group of experts in various professions to assist them in the CGP Partnership Process. The Partnership Process shall be designed to achieve the following:

(i) To ensure that residents are fully briefed and involved in developing the content of, and monitoring the implementation of, the comprehensive plan including, but not limited to, the physical and management needs assessments, viability analysis, Five-Year Action Plan, and Annual Statement. If necessary, the PHA shall develop and implement capacity building strategies to ensure meaningful resident participation in CGP. Such technical assistance efforts for residents are eligible management improvement costs under CGP;

(ii) To enable residents to participate, on a PHA-wide or area-wide basis, in ongoing discussions of the comprehensive plan and strategies for its implementation, and in all meetings necessary to ensure meaningful participation.

(3) *Public notice.* Within a reasonable amount of time before the advance meeting for residents under paragraph (b)(4) of this section and the public hearing under paragraph (b)(5) of this section, the PHA shall provide public notice of the advance meeting and the public hearing in a manner determined by the PHA that ensures notice to all duly elected resident councils.

(4) *Advance meeting for residents.* The PHA shall hold, within a reasonable amount of time before the public hearing under paragraph (b)(5) of this section, a meeting for residents and duly elected resident councils at which the PHA shall explain the components of the comprehensive plan. The meeting shall be open to all residents and duly elected resident councils.

(5) *Public hearing.* The PHA shall hold at least one public hearing, and any appropriate number of additional

hearings, to present information on the comprehensive plan/annual submission and the status of prior approval programs. The public hearing shall provide ample opportunity for residents, local government officials, and other interested parties to express their priorities and concerns. The PHA shall give full consideration to the comments and concerns of residents, local government officials, and other interested parties.

(c) *Local government participation.* A PHA shall consult with and provide information to appropriate local government officials with respect to the development of the comprehensive plan to ensure that there is coordination between the actions taken under the consolidated plan (see 24 CFR part 91) for project and neighborhood improvements where public housing units are located or proposed for construction and/or modernization and improvement and to coordinate meeting public and human service needs of the public and assisted housing projects and their residents. In the case of a PHA with developments in multiple jurisdictions, the PHA may meet this requirement by consulting with an advisory group representative of all the jurisdictions. At a minimum, such consultation must include providing such officials with:

(1) Advance written notice of the public hearing required under paragraph (b)(5) of this section;

(2) A copy of the summary of total preliminary estimated costs to address physical needs by each development and management/operations needs PHA-wide and a specific description of the PHA's process for maximizing the level of participation by residents and a summary of the general issues raised on the plan by residents and others during the public comment process and the PHA's response to the general issues. PHA records, such as minutes of planning meetings or resident surveys, shall be maintained in the PHA's files and made available to residents, resident organizations, and other interested parties upon request; and

(3) An opportunity to express their priorities and concerns to ensure due consideration in the PHA's planning process;

(d) *Participation in coordinating entities.* To the extent that coordinating entities are set up to plan and implement the consolidated plans (under 24 CFR part 91), the PHA shall participate in these entities to ensure coordination with broader community development strategies.

(e) *Contents of comprehensive plan.* The comprehensive plan shall identify

all of the physical and management improvements needed for a PHA and all of its developments, and that represent needs eligible for funding under § 968.112. The plan also shall include preliminary estimates of the total cost of these improvements. The plan shall set forth general strategies for addressing the identified needs, and highlight any special strategies, such as major redesign or partial demolition of a development, that are necessary to ensure the long-term physical and social viability of the development. Where long-term physical and social viability of the development is dependent upon revitalization of the surrounding neighborhood in the provision of or coordination of public services, or the consolidation or coordination of drug prevention and other human service initiatives, the PHA shall identify these needs and strategies. In addition, the PHA shall identify the funds or other resources in the consolidated plan that are to be used to help address these needs and strategies and the activities in the comprehensive plan that strengthen the consolidated plan. Each comprehensive plan shall contain the following elements:

(1) *Executive summary.* A PHA shall include as part of its comprehensive plan an executive summary to facilitate review and comprehension by development residents and by the public. The executive summary shall include the following:

(i) A summary of total preliminary estimated costs to address physical needs by each development and PHA-wide physical and management needs; and

(ii) A specific description of the PHA's process for maximizing the level of participation by residents during the development, implementation and monitoring of the Comprehensive Plan, a summary of the general issues raised on the plan by residents and others during the public comment process and the PHA's response to the general issues. PHA records, such as minutes of planning meetings or resident surveys, shall be maintained in the PHA's files and made available to residents, duly elected resident councils, and other interested parties, upon request;

(2) *Physical needs assessment.* (i) *Requirements.* The physical needs assessment identifies all of the work that a PHA would need to undertake to bring each of its developments up to the modernization and energy conservation standards, as required by the Act, to comply with lead-based paint testing and abatement requirements under this part, and to comply with other program requirements under § 968.110. The

physical needs assessment is completed without regard to the availability of funds, and shall include the following:

(A) A brief summary of the physical improvements necessary to bring each such development to a level at least equal to applicable HUD standards with respect to modernization standards, energy conservation and life-cycle cost effective performance standards, lead-based paint testing and abatement standards. This summary must indicate the relative urgency of need. If the PHA has no physical improvement needs at a particular development at the time it completes its comprehensive plan, it must so indicate. Similarly, if the PHA intends to demolish, partially demolish, convert, or dispose of a development (or units within a development) it must so indicate in the summary of physical improvements;

(B) The replacement needs of equipment systems and structural elements that will be required to be met (assuming routine and timely maintenance is performed) during the period covered by the action plan;

(C) A preliminary estimate of the cost to complete the physical work;

(D) Any physical disparities between buildings occupied predominantly by one racial or ethnic group and, in such cases, the physical improvements required to correct the conditions; and

(E) In addition, with respect to vacant or non-homebuyer occupied Turnkey III units, the estimated number of units that the PHA is proposing for substantial rehabilitation and subsequent sale, in accordance with § 968.112(d)(3).

(ii) *Source of data.* The PHA shall identify in its needs assessment the sources from which it derived data to develop the physical needs assessment under this paragraph (e)(2) and shall retain such source documents in its files;

(3) *Management needs assessment (i) Requirements.* The plan shall include a comprehensive assessment of the improvements needed to upgrade the management and operation of the PHA and of each viable development so decent, safe, and sanitary living conditions will be provided. The management needs assessment shall include the following, with the relative urgency of need indicated:

(A) An identification of the most current needs related to the following areas (to the extent that any of these needs is addressed in a HUD-approved memorandum of agreement or improvement plan, the PHA may simply include a cross-reference to these documents):

(1) The management, financial, and accounting control systems of the PHA;

(2) The adequacy and qualifications of personnel employed by the PHA in its management and operation, for each significant category of employment;

(3) The adequacy and efficacy of:

(i) Resident programs and services;

(ii) Resident and development security;

(iii) Resident selection and eviction;

(iv) Occupancy;

(v) Maintenance;

(vi) Resident management and resident capacity building programs;

(vii) Resident opportunities for employment and business development and other self-sufficiency opportunities for residents; and

(viii) Homeownership opportunities for residents;

(B) Any additional deficiencies identified through PHMAP, audits and HUD monitoring reviews that are not addressed under paragraph (e)(3)(i)(A) of this section. To the extent that any of these is addressed in a HUD-approved memorandum of agreement or improvement plan, the PHA may include a cross-reference to these documents;

(C) Any other management and operations needs that the PHA wants to address at the PHA-wide or development level; and

(D) A PHA-wide preliminary cost estimate for addressing all the needs identified in the management needs assessment, without regard to the availability of funds;

(ii) *Sources of funds.* The PHA shall identify in its needs assessment the sources from which it derived data to develop the management needs assessment under this paragraph (e)(3) and shall retain such source documents in its files;

(4) *Demonstration of long-term physical and social viability.* (i) *General.* The plan shall include, on a development-by-development basis, an analysis of whether completion of the improvements and replacements identified under paragraphs (e)(2) and (e)(3) of this section will reasonably ensure the long-term physical and social viability, including achieving structural/system soundness and full occupancy, of the development at a reasonable cost. For cost reasonableness, the PHA shall determine whether the unfunded hard costs satisfy the definition of "reasonable cost." Where the PHA wishes to fund a development, for other than emergencies, where hard costs exceed that reasonable cost, the PHA shall submit written justification to the Field Office. If the Field Office agrees with the PHA's request, the Field Office

shall forward its recommendation to Headquarters for final decision. Where the estimated per unit unfunded hard cost is equal to or less than the per unit TDC for the smallest bedroom size at the development, no further computation of the TDC limit is required. The PHA shall keep documentation in its files to support all cost determinations. The Field Office will review cost reasonableness as part of its review of the annual submission and the performance and evaluation report. As necessary, HUD will review the PHA's documentation in support of its cost reasonableness, taking into account broader efforts to revitalize the neighborhoods in which the development is located;

(ii) *Determination of non-viability.*

Where a PHA's analysis of a development under paragraph (e) of this section establishes that completion of the identified improvements and replacements will not result in the long-term physical and social viability of the development at a reasonable cost, the PHA shall not expend CGP funds for the development, except for emergencies and essential non-routine maintenance necessary to maintain habitability until residents can be relocated. The PHA shall specify in its comprehensive plan the actions it proposes to take with respect to the non-viable development (e.g., demolition or disposition under 24 CFR part 970);

(5) *Five-year action plan.* (i) *General.* The comprehensive plan shall include a rolling five-year action plan to carry out the improvements and replacements (or a portion thereof) identified under paragraphs (e)(2) and (e)(3) of this section. In developing its five-year action plan, the PHA shall assume that the current year funding or formula amount will be available for each year of its five-year action plan, whichever the PHA is using for planning purposes, plus the PHA's estimate of the funds that will be available from other sources, such as state and local governments. All activities specified in a PHA's five-year action plan are contingent upon the availability of funds;

(ii) *Requirements.* Under the action plan, a PHA must indicate how it intends to use the funds available to it under the CGP to address, over a five-year period, the deficiencies (or a portion of the deficiencies) identified in its physical and management needs assessments, as follows:

(A) *Physical condition.* With respect to the physical condition of a PHA's developments, a PHA must indicate in its action plan how it intends to address, over a five-year period, the



deficiencies (or a portion of the deficiencies) identified in its physical needs assessment so as to bring each of its developments up to a level at least equal to the modernization and energy conservation standards. This includes specifying the work to be undertaken by the PHA in major work categories (e.g., kitchens, electrical systems, etc.); establishing priorities among the major work categories by development and year, based upon the relative urgency of need; and estimating the cost of each of the identified major work categories. In developing its action plan, a PHA shall give priority to the following:

(1) Activities required to correct emergency conditions;

(2) Activities required to meet statutory or other legally mandated requirements (e.g., compliance with a court-ordered desegregation plan or voluntary compliance agreement);

(3) Activities required to meet the needs identified in the Section 504 needs assessment within the regulatory timeframe; and

(4) Activities required to complete lead-based paint testing and abatement requirements;

(B) *Management and operations.* A PHA must address in its action plan the management and operations deficiencies (or a portion of the deficiencies) identified in its management needs assessment, as follows:

(1) With respect to the management and operations needs of the PHA, the PHA must identify how it intends to address with CGP funds, if necessary, the deficiencies (or a portion thereof) identified in its management needs assessment, including work identified through PHMAP, audits, HUD monitoring reviews, and self-assessments. The action plan must indicate the relative urgency of need;

(2) A preliminary PHA-wide cost estimate, by major work category.

(iii) *Procedure for maintaining current five-year action plan.* The PHA shall maintain a current five-year action plan by annually amending its five-year action plan, in conjunction with the annual submission;

(6) *Local government statement.* The comprehensive plan shall include a statement signed by the chief executive officer of the unit of general local government (or, in the case of a PHA with developments in multiple jurisdictions, from the CEO of each such jurisdiction) certifying to the following:

(i) The PHA developed the comprehensive plan/five-year action plan or amendments thereto in consultation with officials of the appropriate governing body and with

development residents covered by the comprehensive plan/five-year action plan, in accordance with the requirements of paragraphs (b) and (c) of this section;

(ii) The comprehensive plan/five-year action plan or amendments thereto are consistent with the appropriate governing body's assessment of its low income housing needs (as evidenced by its consolidated plan under 24 CFR part 91, if applicable), and that the appropriate governing body will cooperate in providing resident programs and services; and

(iii) The PHA's proposed drug elimination activities are coordinated with, and supportive of, local drug elimination strategies and neighborhood improvement programs, if applicable; and

(7) *PHA resolution.* The plan shall include a resolution, in a form prescribed by HUD, adopted by the PHA Board of Commissioners, and signed by the Board Chairman of the PHA, approving the comprehensive plan or any amendments.

(f) *Amendments to the comprehensive plan.*—(1) *Extension of time for performance.* A PHA shall have the right to amend its comprehensive plan (including the action plan) to extend the time for performance whenever HUD has not provided the amount of assistance set forth in the comprehensive plan or has not provided the assistance in a timely manner;

(2) *Amendments to needs assessments.* The PHA shall amend its plan by revising its needs assessments whenever it proposes to carry out activities in its five-year action plan or annual statement that are not reflected in its current needs assessments (except in the case of emergencies). The PHA may propose an amendment to its needs assessments, in connection with the submission of its annual submission (see § 968.325) or at any other time. These amendments shall be reviewed by HUD in accordance with § 968.320.

(3) *Six-year revision of comprehensive plan.* Every sixth year following the initial year of participation, the PHA shall submit to HUD, with its annual submission, a complete update of its comprehensive plan. A PHA may elect to revise some or all parts of the comprehensive plan more frequently.

(4) *Annual revision of five-year action plan.* Annually, the PHA shall submit to HUD, with its annual submission, an update of its five-year action plan, eliminating the previous year and adding an additional year. The PHA shall identify changes in work categories (other than those included in the new fifth year) from the previous

year five-year action plan when making this annual submission.

(5) *Required submissions.* Any amendments to the comprehensive plan under this section must be submitted with the PHA resolution under § 968.315(e)(7).

(g) *Prerequisite for receiving assistance.*—(1) *Prohibition of assistance.* No financial assistance, except for emergency work to be funded under §§ 968.103(b) and 968.112(a)(1)(ii), and for modernization needs resulting from disasters under § 968.103(b), may be made available under this subpart unless HUD has approved a comprehensive plan submitted by the PHA that meets the requirements of this section. A PHA that has failed to obtain approval of its comprehensive plan by the end of the FFY shall have its formula allocation for that year (less any formula amounts provided to the PHA for emergencies) added to the subsequent year's appropriation of funds for grants under this part. HUD shall allocate such funds to PHAs and IHAs participating in the CGP in accordance with the formula under § 968.103(e) and (f) in the subsequent FFY. A PHA that elects in any FFY not to participate in the CGP may participate in the CGP in subsequent FFYs;

(2) *Requests for emergency assistance.* A PHA may receive funds from its formula allocation to address emergency modernization needs where HUD has not approved a PHA's comprehensive plan. To request such assistance, a PHA shall submit to HUD a request for funds in such form as HUD may prescribe, including any documentation necessary to support its claim that an emergency exists. HUD shall review the request and supporting documentation to determine if it meets the definition of "emergency work" as set forth in § 968.305. (Approved by the Office of Management and Budget under control number 2577-0157)

#### **§ 968.320 [Removed]**

33. Section 968.320 is removed.

#### **§ 968.325 [Redesignated as § 968.320]**

34. Section 968.325 is redesignated as § 968.320; and newly redesignated § 968.320 is amended by:

a. Removing from paragraph (a)(1)(i) the reference to "§ 968.320(d)" and adding in its place a reference to "§ 968.315(e)";

b. Removing from paragraph (c) the references to "§ 968.340" and "§ 968.345" and adding in their place references to "§ 968.330" and "§ 968.335", respectively; and



c. Revising paragraph (b)(2) to read as follows:

**§ 968.320 HUD review and approval of comprehensive plan (including five-year action plan).**

\* \* \* \* \*

(b) \* \* \*

(2) HUD shall approve the Comprehensive Plan except where it makes a determination in accordance with one or more of the following:

(i) Comprehensive Plan is incomplete in significant matters;

(ii) Identified needs are plainly inconsistent with facts and data;

(A) Identified physical improvements and replacements are inadequate;

(B) Identified management improvements are inadequate;

(C) Proposed physical and management improvements fail to address identified needs;

(iii) Action plan is plainly inappropriate to meeting identified needs;

(iv) Inadequate demonstration of long-term viability at reasonable cost; and

(v) Contradiction of local government certification or PHA resolution.

\* \* \* \* \*

**§ 968.330 [Redesignated as § 968.325]**

35. Section 968.330 is redesignated as § 968.325; and newly redesignated § 968.325 is amended by:

a. Removing from paragraph (a) the reference to “§ 968.315(b)(1)” and adding in its place a reference to “§ 968.310(b)(1)” and by moving the phrase “, as discussed in § 968.320(d)(5)(i)” from the end of the penultimate sentence in the paragraph to the end of the sentence before it, and revising the number “§ 968.320” in that phrase to read “§ 968.315”;

b. Removing from paragraph (d) introductory text the reference to

“§ 968.320” and adding in its place a reference to “§ 968.315”;

c. Removing from paragraph (e)(8) the reference to “§ 968.320(d)(7)” and adding in its place a reference to “§ 968.315(e)(7)”;

d. Removing from paragraph (f) references to “§ 968.320(e)” and “§ 968.325” and adding in their place references to “§ 968.315(f)” and “§ 968.320”;

e. Removing from paragraph (g)(2)(ii) the reference to “§ 968.320(d)” and adding in its place a reference to “§ 968.315(e)”;

f. Removing from paragraph (h) the reference to “§ 968.305” and adding in its place a reference to “§ 968.330”;

g. Removing from paragraph (i)(1) references to “§ 968.345” and adding in their place references to “§ 968.335”;

h. Removing from paragraph (j) the words “to obtain” and adding in their place the words “in order for the PHA to draw down”; and

i. Revising the section heading and paragraph (e)(4), to read as follows:

**§ 968.325 Annual submission of activities and expenditures.**

\* \* \* \* \*

(e) \* \* \*

(4) For each development and for any management improvements not covered by a HUD-approved memorandum of agreement or management improvement plan, a schedule for the use of current year funds, including target dates for the obligation and expenditure of the funds (see § 968.125);

\* \* \* \* \*

**§ 968.335 [Removed]**

36. Section 968.335 is removed.

**§ 968.340 [Redesignated as § 968.330]**

37. Section 968.340 is redesignated as § 968.330, and newly redesignated § 968.330 is amended by removing the

paragraph designation and heading from paragraph (a), and by removing paragraph (b).

**§ 968.345 [Redesignated as § 968.335]**

38. Section 968.345 is redesignated as § 968.335; and newly redesignated § 968.335 is amended by:

a. Removing paragraphs (a)(1)(i) and (a)(1)(ii), paragraphs (a)(2)(i) and (a)(2)(ii), and paragraphs (a)(3)(i) through (a)(3)(iii);

b. Removing from paragraph (d) the reference to “§ 905.684” and adding in its place a reference to “§ 968.330”;

c. Removing from paragraph (e)(7) the words “(see § 968.315(d))”;

d. Removing from paragraph (g) references to “§ 905.135” and “§ 905.601” and adding in their place references to “§ 950.135” and “§ 968.103(e) and (f)”, respectively;

e. Removing from paragraph (j) references to “§ 978.345(h)” and “§ 968.345(g)” and adding in their place references to “paragraph (h) of this section” and “paragraph (g) of this section”, respectively; and

f. Removing the reference in paragraph (k) to “§ 968.312(c)” and adding in its place a reference to “§ 968.310(c)”.

**Subpart D—Vacancy Reduction Program**

**§§ 968.401, 968.403, 968.405, 968.407, 968.410, and 968.413 [Removed]**

39. Sections 968.401, 968.403, 968.405, 968.407, 968.410, and 968.413 are removed.

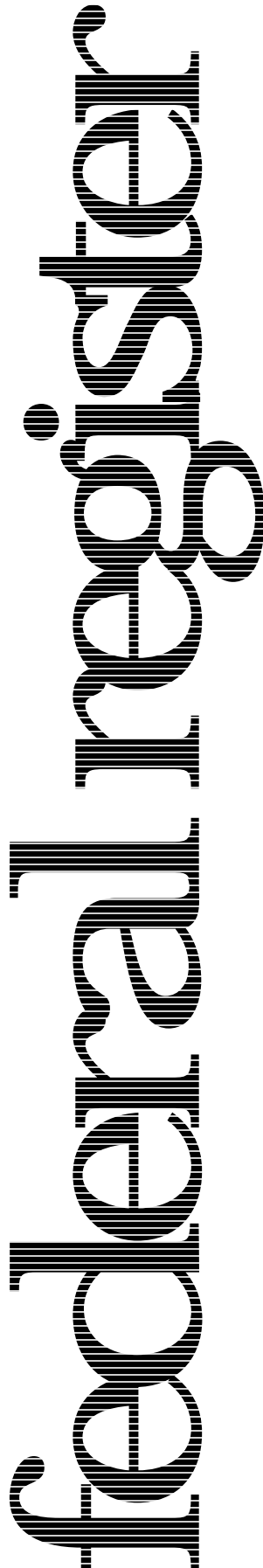
Dated: February 8, 1996.

Michael B. Janis,

*General Deputy Assistant Secretary for Distressed and Troubled Housing Recovery.*

[FR Doc. 96-4814 Filed 3-4-96; 8:45 am]

BILLING CODE 4210-33-P



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Tuesday  
March 5, 1996

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## Part III

# Department of Health and Human Services

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### Food and Drug Administration

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#### 21 CFR Part 101

Food Labeling: Health Claims and Label Statements; Folate and Neural Tube Defects; Proposed Rule and Final Rule

#### 21 CFR Part 136, 137, and 139

Food Standards: Amendment of Standards of Identity for Enriched Grain Products To Require Addition of Folic Acid; Final Rule

#### 21 CFR Part 172

Food Additives Permitted for Direct Addition to Food for Human Consumption; Folic Acid (Folacin); Final Rule

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

### 21 CFR Part 101

[Docket No. 93N-0481]

RIN 0910-AA23

### Food Labeling: Health Claims and Label Statements; Folate and Neural Tube Defects; Revocation

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to revoke a regulation authorizing a health claim on the relationship between folic acid and neural tube defects (NTD's) on the labels and in the labeling of dietary supplements that became final by operation of law. The agency intends to replace this revoked regulation with one that is published elsewhere in this issue of the Federal Register. This action is being taken to ensure that the regulation that authorizes claims on this nutrient-disease relationship is fully responsive to the public comments that FDA has received on this matter.

**DATES:** Written comments by April 4, 1996. The agency is proposing that any final rule that may issue based on this proposal become effective on the date of publication of the final rule in the Federal Register.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Jeanne I. Rader, Center for Food Safety and Applied Nutrition (HFS-175), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5375.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101-535) amended the Food, Drug, and Cosmetic Act (the act) to give the Secretary of the Department of Health and Human Services (the Secretary), and by delegation FDA, the authority to issue regulations authorizing health claims on the labels and in the labeling of foods. Section 403(r)(1)(B) of the act (21 U.S.C. 343(r)(1)(B)) provides that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in

accordance with procedures and standards established under section 403(r)(3) and (r)(5)(D) of the act.

The 1990 amendments also directed the Secretary to determine through rulemaking whether claims regarding 10 nutrient-disease relationships met the requirements of the act. The relationship of folic acid and NTD's was among those 10 topics (section 3(b)(1)(A)(x) of the 1990 amendments).

##### A. The 1991 Proposed Rule

In the Federal Register of November 27, 1991 (56 FR 60537), FDA proposed to not authorize a health claim on folic acid and NTD's. The agency tentatively concluded that the available evidence did not establish that the standard that FDA had proposed for health claims for dietary supplements under section 403(r)(5)(D) of the act was met; that is, that there was not significant scientific agreement, based on the totality of publicly available scientific evidence, that the claim is valid.

##### B. The Public Health Service Recommendations

In September 1992, following the availability of significant new data, the Public Health Service (PHS) issued a recommendation that all women of childbearing age in the United States who are capable of becoming pregnant should consume 0.4 milligram (mg) of folic acid per day for the purpose of reducing their risk of having a pregnancy affected with spina bifida or other NTD's. The recommendation was based on data suggesting that folic acid, when given at a high dose (4 mg), can reduce the risk of recurrence of NTD's and on studies that used multivitamins containing folic acid at dose levels from 0 to 1,000 micrograms per day. The PHS recommendation identified approaches and identified outstanding issues, including the recommended intake of folate, the potential role of other nutrients in reduction of risk of NTD's, safety concerns, and the "folate-preventable" fraction of NTD's.

##### C. The Dietary Supplement Act of 1992

In October 1992, the Dietary Supplement Act of 1992 (the DS act) was enacted. This statute imposed a moratorium on FDA's implementation of the 1990 amendments with respect to dietary supplements until December 15, 1993. The DS act directed FDA to issue proposed rules to implement the 1990 amendments with respect to dietary supplements by June 15, 1993, and to issue final rules based on these proposals by December 31, 1993. The DS act also amended the so-called "hammer" provision of the 1990

amendments, section 3(b)(2) of the 1990 amendments, to provide that if the agency did not meet the established December 31, 1993, timeframe for issuance of final rules, the proposed regulations would be considered final regulations.

##### D. The 1993 Final Rules for Health Claims for Food in Conventional Food Form

In the Federal Register of January 6, 1993 (58 FR 2606), FDA published a final rule to not authorize a health claim for folic acid and NTD's. However, the agency reaffirmed its support of the PHS recommendation that all women of childbearing age in the United States who are capable of becoming pregnant should consume 0.4 mg of folic acid daily to reduce their risk of having a pregnancy affected with spina bifida or other NTD's. The agency noted, however, that unresolved questions about the safe use of folate remained. The agency concluded that it could not authorize a health claim until these questions were resolved. Because of the DS act, FDA took no final action with respect to the use of a health claim on folic acid and NTD's on dietary supplements.

##### E. The 1993 Proposal to Authorize a Health Claim on Folic Acid and NTD's

In the Federal Register of October 14, 1993 (58 FR 53254), FDA published a proposed rule to authorize the use of a health claim about the relationship of folate and NTD's on the labels of foods in conventional food form and dietary supplements. FDA tentatively concluded, based on its discussions with an advisory committee, that it could ensure the safe use of folate. FDA provided 60 days for comment on this proposed action. The comment period closed on December 13, 1993.

##### F. The 1994 Final Rule

Section 3(b)(2) of the 1990 amendments, as amended by section 202(a)(2)(B)(ii) of the DS act, provides that if the Secretary does not promulgate final regulations on any of the health claims applicable to dietary supplements in a timely manner, the proposed regulations shall be considered final regulations but not until December 31, 1993. Because FDA was unable to publish a final rule by December 31, 1993, in the proceeding instituted in October of 1993, FDA published a notice in the Federal Register of January 4, 1994 (59 FR 433), announcing that the regulation that it had proposed in the October 1993 folate/NTD proposal was considered to be a final regulation for dietary

supplements by operation of law, effective July 1, 1994.

This document did not conclude the rulemaking begun in October of 1993, however. Rather, the January 4, 1994, document was part of a separate proceeding that is compelled under section 3(b)(2) of the 1990 amendments (see H. Rept. 101-538, 101st Cong., 2d Sess. 18 and 136 Congressional Record 5842 on the effect of this "hammer" provision).

In the January 4, 1994 document, FDA stated that the rulemaking that it instituted in October of 1993 was ongoing, and that it intended to issue a final rule that would resolve the issues in that ongoing proceeding. Elsewhere in this issue of the Federal Register, FDA is issuing a final rule to conclude that proceeding. Given that FDA has now issued that final rule, the regulation that resulted must to supersede the regulation that became final by operation of law. The agency is now instituting this rulemaking to bring about this supersession.

## II. The Proposal

FDA is proposing to withdraw the regulation that became final by operation of law on January 4, 1994 (the January 4, 1994, regulation). FDA tentatively finds that this action is in the best interests of consumers, manufacturers, and regulatory officials for several reasons.

The January 4, 1994, regulation did not have the benefit of public comment. It reflects FDA's initial views on the folic acid/NTD health claim and what it should say. From the comments received in response to the folic acid/NTD health claim proposal, it is clear that the January 4, 1994, regulation does not adequately address several issues related to this health claim. Because the regulation included in the final rule published elsewhere in this issue of the Federal Register addresses the comments that the agency received and includes changes that the agency has made in response to those comments, FDA tentatively finds that that regulation is better able to implement the act than the January 4, 1994, regulation, and that it provides for a more useable and scientifically valid health claim.

FDA tentatively finds that replacing the January 4, 1994, regulation with the regulation included in the final rule will not result in any hardship to

manufacturers who have relied on the January 4, 1994, regulation. The regulation in the final rule in most respects is consistent with the January 4, 1994, regulation. The only differences are those modifications that have been made to shorten the claim and to provide more flexibility to those who decide to use it on their labels or in their labeling. Thus, replacing the January 4, 1994, regulation with the final regulation published elsewhere in this issue of the Federal Register will not present manufacturers with a situation in which they must adjust to a dramatic shift in the standard that they must meet.

FDA is also proposing to limit the comment period to 30 days, and to make any final rule that issues in this proceeding effective on the date of publication. FDA is proposing both of these actions for the same reason. FDA believes that, if the regulation in the final rule is to supersede the January 4, 1994, regulation, this action should proceed as expeditiously as possible. Expeditious action will minimize the possibility for confusion and ambiguity created by this action. FDA tentatively finds that the proposed steps are necessary to facilitate expeditious action, and thus that there is good cause for both of these proposed actions.

## III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental statement is required.

## IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because FDA has fully assessed the economic impact of replacing the January 4, 1994, regulation with the regulation contained in the final rule and has determined this proposal will impose no costs, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

## V. Comments

Interested persons may, on or before April 4, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

## List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

## PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

### § 101.79 [Removed]

2. Section 101.79 *Health claims: folate and neural tube defects* is removed.

Dated: February 26, 1996.

David A. Kessler,

*Commissioner of Food and Drugs.*

Donna E. Shalala,

*Secretary of Health and Human Services.*

[FR Doc. 96-5011 Filed 2-20-96; 12:01pm]

BILLING CODE 4160-01-F

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

### 21 CFR Part 101

[Docket No. 91N-100H]

RIN 0910-AA19

### Food Labeling: Health Claims and Label Statements; Folate and Neural Tube Defects

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is authorizing the use on the labels and in the labeling of food, including dietary supplements, of health claims on the association between adequate intake of folate and the risk of neural tube birth defects. This rule is issued in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims. The agency has concluded that, based on the totality of the publicly available scientific evidence, there is significant scientific agreement among qualified experts that, among women of childbearing age in the general U.S. population, maintaining adequate folate intakes, particularly during the periconceptional interval, may reduce the risk of a neural tube birth defect-affected pregnancy.

**EFFECTIVE DATE:** April 19, 1996.

**FOR FURTHER INFORMATION CONTACT:** Jeanne I. Rader, Office of Food Labeling (HFS-175), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5375.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

##### A. Procedural History

##### 1. The 1990 Amendments

The 1990 amendments to the Federal Food, Drug, and Cosmetic Act (the act) provided for extensive changes in the way foods are labeled. Under these amendments, FDA can authorize the use, in the labeling of foods, of health claims that characterize the relationship of a nutrient to a disease or a health-related condition. Section 403(r)(1)(B) of the act (21 U.S.C. 343(r)(1)(B)) provides that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or a health-related condition unless the claim is made in accordance with procedures and standards established under section 403(r)(3) and (r)(5)(D) of

the act. The 1990 amendments required that FDA evaluate 10 nutrient/disease relationships with respect to their appropriateness as the subjects of health claims. The topic of folic acid and neural tube defects was among those 10 topics.

In the Federal Register of November 27, 1991 (56 FR 60537), in conformity with the requirements of the 1990 amendments, the agency proposed to establish general principles that would govern the appropriateness and validity of health claims on dietary supplements as well as on foods in conventional food form. The agency also proposed to authorize four health claims and to not authorize six others, including a claim on folate and neural tube defects.

##### 2. The Dietary Supplement Act of 1992 (DS Act)

In October of 1992, the Dietary Supplement Act (DS Act; Title II of Pub. L. 102-571) was enacted. It imposed a moratorium until December 15, 1993, on FDA implementation of the 1990 amendments with respect to dietary supplements. The DS Act directed FDA to issue proposed rules to implement the 1990 amendments with respect to dietary supplements by June 15, 1993, and to issue final rules based on these proposals by December 31, 1993.

The DS Act also amended the so-called "hammer" provision of the 1990 amendments to provide that, if the agency did not meet the established December 31, 1993, timeframe for issuance of final rules, the proposed regulations would be considered final regulations.

Accordingly, when FDA issued its final rules on health claims in the Federal Register of January 6, 1993 (58 FR 2478), they did not cover dietary supplements.

##### 3. The 1993 Final Rules

On January 6, 1993, FDA published its final rules on general principles for health claims (58 FR 2478) and the 10 nutrient disease-relationships (58 FR 2537 through 2849). The general principles regulation provides that FDA will issue regulations authorizing health claims only when it determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles) that there is significant agreement, among experts qualified by training or experience to evaluate such claims, that the claim is supported by the scientific evidence.

On January 6, 1993, the agency also issued regulations announcing its

decisions with respect to conventional foods for each of the 10 nutrient-disease relationships that the 1990 amendments directed it to consider. The agency authorized claims on all foods, including dietary supplements, on seven nutrient-disease relationships: Calcium and osteoporosis; sodium and hypertension; fat and cancer; saturated fat and cholesterol and coronary heart disease (CHD); fiber-containing grain products, fruits, and vegetables and cancer; fruits, vegetables, and grain products that contain fiber and risk of CHD; and fruits and vegetables and cancer.

Because of the DS Act, FDA took no final action with respect to the use on dietary supplements of health claims on dietary fiber and cancer; dietary fiber and CHD; omega-3-fatty acids and CHD; zinc and immune function in the elderly; antioxidant vitamins and cancer; and folic acid and neural tube defects.

With respect to folic acid, the agency explained that, while the Public Health Service (PHS) had recommended that all women of childbearing age in the United States consume 0.4 milligram (mg) of folic acid daily to reduce their risk of having a pregnancy affected with spina bifida or other neural tube defects, PHS had also identified several issues that remained outstanding, including the appropriate level of folic acid in food and safety concerns regarding increased intakes of folic acid. Sections 403(r)(3)(A)(ii), 402(a), and 409 of the act (21 U.S.C. 342(a) and 348) establish that the use of a substance in food must be safe. Questions raised in the PHS recommendation (see 58 FR 2606 at 2609) included the safety of high intakes of folate by the target population as well as by other segments of the population who may unintentionally be exposed to high intakes if overfortification of the food supply with folic acid were to occur as a result of the PHS recommendation. FDA concluded that it could not authorize a health claim on folic acid until the questions regarding the safety of the use of this nutrient, as well as other concerns raised by PHS, were satisfactorily resolved (58 FR 2606 at 2614).

##### 4. The Dietary Supplement Proposals

In the Federal Register of June 18, 1993 (58 FR 33700), FDA published a proposal on health claims on dietary supplements. FDA proposed to revise its food labeling regulations to make dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances subject to the same general requirements that apply to

all other types of food with respect to health claims.

In the Federal Register of October 14, 1993 (58 FR 53296), FDA published a proposal not to authorize health claims on the labels of dietary supplements on five nutrient-disease relationships: Dietary fiber and cancer; dietary fiber and CHD; antioxidant vitamins and cancer; omega-3 fatty acids and CHD; and zinc and immune function in the elderly. However, in the same issue of the Federal Register (58 FR 53254), the agency did propose to authorize the use on the labels and labeling of conventional foods and dietary supplements of a health claim on the relationship between folate and risk of neural tube defects and to provide for safe use of folic acid in foods by amending several of its regulations that permit use of folic acid in foods (see also 58 FR 53305 and 58 FR 53312).

#### 5. The Dietary Supplement Health Claim Final Rule

In the Federal Register of January 4, 1994 (59 FR 395), FDA announced that it was amending its food labeling regulations to make dietary supplements subject to the same general requirements that apply to all other types of food with respect to the use on the label or in labeling of health claims that characterize the relationship of a substance to a disease or health-related condition.

Also in the Federal Register of January 4, 1994 (59 FR 433), the agency announced that, in accordance with the 1990 amendments, as amended by the DS Act, the regulation on folate and neural tube defects that it proposed on October 14, 1993 (58 FR 53254), was considered a final regulation for dietary supplements of vitamins, minerals, herbs, and other similar nutritional substances (dietary supplements). In its notice, the agency stated that the document was part of a separate rulemaking contemplated by Congress if a final regulation on the proposal issued on October 14, 1993, was not issued by December 31, 1993, and noted that the notice bore a separate docket number (i.e., No. 93N-0481) to distinguish it from the one assigned to the October 14, 1993 rulemaking (i.e., No. 91N-100H), which, the agency said, was ongoing.

In this document, FDA is finalizing its October 14, 1993, proposal to authorize health claims on the relationship between folate and neural tube defects. This final rule pertains to conventional food as well as to dietary supplements. Elsewhere in this issue of the Federal Register, FDA is proposing to revoke the regulation on this nutrient-disease

relationship that became final by operation of law.

#### 6. The Dietary Supplement Health and Education Act of 1994

The President signed the Dietary Supplement Health and Education Act of 1994 (Pub. L. 103-417) (hereinafter referred to as the DSHEA) into law on October 25, 1994. Among other things, the DSHEA defines "dietary supplements" (in section 3(a)).

In the October 14, 1993, proposal, FDA used the terms "dietary supplements of vitamins, minerals, herbs, and other nutritional substances" and "food in conventional food form." Under the changes effected by the DSHEA (see sections 3 (a) and (c) of the DSHEA), the form of a product is no longer determinative of whether the product is a dietary supplement. Accordingly, with the exception noted below, FDA will use the terms "food" or "foods" in this document to reflect this change and the act's definition of "dietary supplements." FDA will use the terms "conventional food" and "dietary supplement" in response to comments dealing with the bioavailability of folate, for which a distinction needs to be made between foods and dietary supplements. Where other terminology was used in the regulatory language of the October 14, 1993, proposal, FDA has modified that language to conform to the changes effected by DSHEA.

#### B. Relationship Between Folate and Neural Tube Defects

The agency reviewed and updated the scientific literature on the relationship between folate and neural tube defects in the Federal Register of November 27, 1991 (56 FR 60610), January 6, 1993 (58 FR 2606), and October 14, 1993 (58 FR 53254), and provides only a brief summary here.

**Folate.** The term "folate," as used in this document, includes the entire group of folate vitamin forms: That is, folic acid (pteroylglutamic acid), the form of the vitamin added to dietary supplements and to fortified foods, and the naturally-occurring folylpolyglutamates (pteroylpolylglutamates) which are found in foods. "Folate" is thus the general term used to include any form of the vitamin, without reference to the state of reduction, degree of substitution, or number of glutamates. As a vitamin, folate functions metabolically in the synthesis of amino acids and nucleic acids. Insufficient quantities of folate in the diet lead to impaired cell multiplication and alterations in protein synthesis (Ref. 1).

These effects are most noticeable in rapidly growing or dividing cell populations (Ref. 1). Pregnancy increases the need for folate and many other nutrients because of the need of the mother to maintain adequate nutrition and to meet the nutritional requirements of the developing fetus.

**Neural tube defects.** Neural tube defects are serious birth defects that can result in infant mortality or serious disability. The birth defects anencephaly and spina bifida are the most common forms of neural tube defects and account for about 90 percent of these defects. These defects result from failure of closure of the covering of the brain or spinal cord during early embryonic development. The neural tube forms between the 18th and 20th days of pregnancy and closes between the 24th and 27th days. Because the neural tube forms and closes during early pregnancy, the defect may occur before a woman realizes that she is pregnant.

Each year, about 2,500 cases of neural tube defects occur among about 4 million births in the United States (i.e., in approximately 6 of 10,000 births annually). Recent data from State-based birth defects surveillance systems show declining trends for neural tube defects in the United States for about the last 30 years (Ref. 2). The Maternal and Child Health Bureau of the Health Resources and Services Administration reported that the neural tube defect rate in the United States has declined from 1.3 per 1,000 live births in 1970 to 0.6 per 1,000 live births in 1989 (Ref. 3).

The majority of neural tube defects are isolated defects and are believed to be caused by multiple factors. About 90 percent of infants with a neural tube defect are born to women who do not have a family history of these defects. Neural tube defects have been reported to vary with a wide range of factors including genetics, geography, socioeconomic status, maternal birth cohort, month of conception, race, nutrition, and maternal health, including maternal age and reproductive history (Ref. 4). Women with a close relative (i.e., sibling, niece, nephew) with a neural tube defect, with insulin-dependent diabetes mellitus, and with seizure disorders who are being treated with valproic acid or carbamazepine are at significantly increased risk compared with women without these characteristics. Rates for neural tube defects also vary within the United States, with lower rates observed on the west coast than on the east coast.

Several lines of evidence led to the hypothesis that nutritional factors might be associated with some human neural

tube defects (see 56 FR 60610, 58 FR 2606, and 58 FR 53254). Among the nutrients that were hypothesized to play a role in reducing the risk of neural tube defects, folate, a B vitamin, received the greatest attention because of associations between folate intake and reduced risk of neural tube defects found in observational studies in humans and because of the well-recognized role of folate in cell division and growth. Because the neural tube forms early in embryonic development, interventions aimed at reducing the risk of these defects must occur periconceptionally (i.e., during the interval extending from at least 1 month before conception and continuing through the first 6 weeks of pregnancy).

In the folate health claim proposal (58 FR 53254), FDA tentatively concluded that the available data show that folate alone may reduce the risk of recurrence of neural tube defects when given periconceptionally at high-dose levels (i.e., 4 mg/day) to women at high risk of such a recurrence. Additionally, based on a synthesis of information from several observational studies that reported periconceptional use of multivitamins containing 0 to 1,000 micrograms (mcg or µg) of folic acid, FDA inferred that folic acid intake at levels of 0.4 mg (400 mcg) per day may reduce the risk of occurrence of neural tube defects. Protective effects measured by reduction in incidence of neural tube defects have been found in several observational studies that reported periconceptional use of multivitamin supplements containing about 400 mcg folic acid.

**Public health significance.** Reduction in adverse pregnancy outcomes such as birth defects is an important public health goal. Because most neural tube defects occur in women without a history of such outcomes, interest in reducing the risk of first occurrences has been very high. PHS has inferred that if all women of childbearing age consumed 0.4 mg (400 mcg) folic acid daily throughout their childbearing years, there might be a reduction in neural tube defects of about 50 percent (i.e., about 1,250 cases per year) (Ref. 5).

#### *C. Regulatory and Other Activities Related to Folate and Neural Tube Defects*

Since the passage of the 1990 amendments in November 1990, the rapidly evolving nature of the science relative to folate and the risk of neural tube defects and a number of PHS activities have intertwined with the regulatory process on the question of whether a health claim should be authorized on this topic. These

developments have resulted in a dynamic process that began with the publication of a proposed rule not to authorize a health claim on folic acid and neural tube defects (56 FR 60610); saw PHS issue a recommendation that all women of childbearing age in the United States should consume 0.4 mg of folic acid per day for the purpose of reducing their risk of having a pregnancy affected with spina bifida or other neural tube defect (Ref. 5); included meetings of FDA's Folic Acid Subcommittee and Food Advisory Committee (Refs. 6 and 7); and was marked by FDA publishing a final rule that noted that, while the PHS recommendation evidenced that significant scientific agreement exists regarding the relationship between folate and neural tube defects, there were significant unresolved questions about the safe use of folic acid in food (58 FR 2606). In its January 6, 1993, Federal Register document, the agency concluded that it could not authorize a health claim for folate until the questions regarding the safe use of this nutrient, as well as other concerns raised by PHS, were satisfactorily resolved.

The process proceeded to the point where, in October 1993, FDA stated that it had tentatively concluded that the safety questions had been resolved, and that there is significant scientific agreement about the validity of the relationship between folate and neural tube defects (58 FR 53254). The agency also tentatively concluded that, based on its discussions with the Folic Acid Subcommittee and its analyses of food intake data, daily folate intakes can be maintained within safe ranges by allocating fortification with folic acid to specific foods in the food supply through an amendment to the food additive regulation for folic acid.

The agency therefore proposed to authorize a health claim relating diets adequate in folate to a reduced risk of neural tube defect-affected pregnancies (58 FR 53254). In companion documents published in the same issue of the Federal Register, the agency also proposed to provide for the safe use of folic acid in foods by amending the food additive regulations for folic acid (58 FR 53312) and to amend the standards of identity for specific enriched cereal-grain products to require the addition of folic acid (58 FR 53305).

The agency convened the Folic Acid Subcommittee and the Food Advisory Committee on October 14 and 15, 1993 (Ref. 8). Members were asked to comprehensively review the October 14, 1993, proposals and to provide comments. The agency requested that

the Folic Acid Subcommittee give priority to the health claim issue because the DS Act required that health claim regulations be finalized by December 31, 1993. The agency treated the discussions of the Folic Acid Subcommittee as comments. A summary of the discussions that occurred during the meetings is provided in the summary of comments below.

As stated above, in January 1994, FDA announced (59 FR 433) that, by operation of law, the regulation that it proposed on October 14, 1993 (58 FR 53254), to authorize the use of a health claim about the relationship between folate and the risk of neural tube defects was a final regulation applicable to the label and labeling of dietary supplements only. The agency also advised that, given the PHS recommendation and the results of the agency's review of the evidence on this claim, in addition to authorizing the claim on dietary supplements, it had no intention of taking action against conventional foods that are naturally high in folate that bear a claim on this nutrient-disease relationship, so long as the claim fully complies with the provisions of the regulation that became final for dietary supplements by operation of law.

#### *D. Scope of This Document*

In the Federal Register of October 14, 1993 (58 FR 53254), the agency posed a series of questions for itself. These questions, and the agency's proposed answers, provided the outline for the October 14, 1993 document. The questions were: (1) Is a health claim on the relationship between folate and neural tube defects appropriate on food labels? (2) If the agency concludes that a health claim can be safely implemented, what should such a claim say about folate and neural tube defects? (3) Should the food supply be fortified with folic acid to ensure that women have adequate folate intakes? If so, is it necessary to limit the foods to which folic acid can be added and the levels at which it can be added to those foods? (4) If there are to be limitations on the foods that can be fortified with folic acid, which foods are most appropriate for fortification, and at what levels should they be fortified?

During the development of this final rule, data on the folate status of the U.S. population obtained during Phase 1 of the Third National Health and Nutrition Examination Survey (NHANES III, Phase 1, 1988–1991) became available. The agency anticipated evaluating red blood cell (RBC) and serum folate data, and data on folate intake from foods and

dietary supplements from this survey. Additionally, because the NHANES III folate consumption data are more current than the data used by the agency in developing its October 14, 1993, proposals for food fortification and for amending the agency's food additive regulation for folic acid (58 FR 53305 and 58 FR 53312, respectively), the agency considered delaying completion of these rulemakings until evaluation of the newer data was complete.

However, in late 1993, FDA became aware of a methodological problem associated with the radioassay kits used in NHANES III (1988 to 1994) that affected serum folate and RBC folate values and, consequently, data interpretation. FDA's Center for Food Safety and Applied Nutrition requested that the Life Sciences Research Office (LSRO), Federation of American Societies for Experimental Biology (FASEB), review, under a contract with FDA, the issues and report its findings to the agency. FDA requested that LSRO/FASEB: (1) Examine the analytical bases of the discrepancies associated with serum folate and RBC folate values derived from use of certain analytical kits used in NHANES III (1988 to 1991); (2) evaluate the scientific basis and validity of procedures proposed by the Centers for Disease Control and Prevention (CDC) to make corrections to serum folate and RBC folate values obtained in NHANES III Phase 1 (1988 to 1991); (3) reexamine current "cutoff" values used for estimation of "deficient," "low status," etc., in light of the need for application of a correction factor; and (4) determine whether these approaches are still useful for estimating the prevalence of inadequate folate nutriture in the U.S. population.

A full description of the problem, the analytical issues involved, the issues that arose that are related to the interpretation of NHANES III Phase 1 (1988 to 1991) data, and LSRO/FASEB's conclusions are presented in "Assessment of Folate Methodology Used in the Third National Health and Nutrition Examination Survey (NHANES III, 1988-1991)" (Ref. 9). A major conclusion of LSRO/FASEB was that neither adjustment of the serum folate or RBC folate data from NHANES III Phase 1 (1988 to 1991) to correct for the analytical problem, the use of the data without adjustment, nor the use of either data set with adjusted criteria for normalcy and deficiency, by themselves, can predict the prevalence of inadequate folate nutriture of the U.S. population.

Based on LSRO/FASEB's report and its own review of the data, the agency

has concluded that while there is a need for further evaluation of the NHANES III (1988 to 1991) serum folate and RBC folate data set, the agency will not delay this rulemaking until such evaluation is complete.

The complete data from NHANES III (1988 to 1994) on folate intake from food and dietary supplements are not yet publicly available. Therefore, the agency cannot evaluate total folate intakes from foods and from dietary supplements from this survey data. The agency has concluded that it will also not delay the fortification and food additive rulemakings until the expected availability of these data in 1996.

## II. Summary of Comments and the Agency's Responses

The agency received nearly 100 comments in response to its October 14, 1993, proposed rule on a health claim on folate and neural tube defects. In addition, as stated above, FDA submitted the transcript of the October 14 and 15, 1993, meetings of the Folic Acid Subcommittee and Food Advisory Committee, in which the proposed rule was discussed, to the docket 91N-100H as a comment (Ref. 8). Comments were received from individual members of FDA's Folic Acid Subcommittee and Food Advisory Committee and invited guest consultants; other Federal agencies; a foreign government; State departments of agriculture, consumer services, or health; health care professionals; consumers; consumer advocacy groups; national organizations of health care professionals; State and territorial public health nutrition directors; manufacturers and suppliers of vitamins to the conventional food industry and the dietary supplement industry; manufacturers of finished foods including breakfast cereals, frozen foods, and bakery products; and trade associations of dietary supplement manufacturers, bakers, millers, and food processors. A number of comments were received that were more appropriately answered in other dockets, and these were forwarded to the appropriate dockets for response.

FDA has considered all of the comments on a health claim on folate and neural tube defects that it received. The agency reviewed all of the documents, including letters, press releases, scientific articles and data supporting these articles, review articles, and recommendations, that were included in the comments. A summary of the comments that the agency received and the agency's responses follow.

### A. *Advisability of Authorizing Health Claims*

1. Some comments endorsed health claims because of their potential educational benefits, while other comments stated that health claims on foods that focus on single nutrients are a bad idea because combinations of foods, not single nutrients, build health. The advisability of health claims was also discussed at the October 14 and 15, 1993, meeting of the Folic Acid Subcommittee (Ref. 8).

The agency notes that the issue of whether health claims should be permitted in food labeling is moot because the 1990 amendments authorized claims on the relationship between substances and diseases or health-related conditions if the scientific validity standard is met.

### B. *Advisability of Authorizing a Health Claim for Folate and Neural Tube Defects*

In § 101.79(c)(2)(i)(A) (21 CFR 101.79(c)(2)(i)(A)), FDA proposed to authorize health claims on labels or in labeling of conventional foods and dietary supplements on the relationship between folate and neural tube defects in women of childbearing age.

#### 1. Scientific Validity Standard: Adequacy of the Scientific Data

2. Many comments supported FDA's tentative decision to authorize a health claim on the relationship between folate and neural tube defects but did not provide any specific reasons for their support. Several comments noted that the scientific basis for the claim was as strong as that used to authorize other claims (e.g., those relating calcium and osteoporosis and saturated fat and heart disease). Members of the Folic Acid Subcommittee who supported a health claim noted that such claims would provide information to the target population, and that such claims tend to be more effective than educational programs alone.

Other comments opposed the health claim, identifying specific concerns with the quality and quantity of the data used to develop the PHS recommendation and to support the proposed health claim. Members of the Folic Acid Subcommittee who opposed a health claim cited the weakness of the data supporting the relationship, including the very small number, and observational nature, of studies relating intake of folate at levels attainable from usual diets to reduced risk of neural tube defects and the many issues associated with the interpretation of these studies (58 FR 53265).



Several comments noted that because of the variety of micronutrients in addition to folic acid contained in supplements whose use was reported in several case-control studies, and because foods high in folate are also important sources of other micronutrients, it is not possible to isolate an independent role for folate in reduction in risk of first occurrences of neural tube defects. Other comments also expressed concern regarding the lack of folate-specific data at intakes of 400 mcg daily and noted that studies showing a positive impact of use of multivitamins containing 400 to 1,000 mcg of folic acid may have been showing a combined effect of folic acid and vitamin B12 or of folic acid and other components of the multivitamin preparations.

A comment noted that there is little knowledge about biological mechanisms that would explain the role of folate in reduction in risk of neural tube defects. The comment stated that it was inappropriate to conclude that, because folic acid alone at a supraphysiologic dose (i.e., 4,000 mcg/day; 4 mg/day) is effective in reducing the risk of neural tube defects among women at recurrent risk, it would also reduce the risk of such defects among women at much lower risk of a first occurrence when consumed at lower doses (i.e., at 400 mcg/day; 0.4 mg/day). Another comment expressed the opinion that the agency should not authorize a claim because there is not significant scientific agreement that the evidence supports the claim.

Section 101.14(c) (21 CFR 101.14(c)) states that the agency will issue a regulation authorizing a health claim when it determines, based on the totality of the publicly available scientific evidence, that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

For folate and neural tube defects, the agency evaluated all of the available scientific evidence, consulted with the Folic Acid Subcommittee and Food Advisory Committee about this evidence, and considered all the information contained in the comments. Based on this review, FDA has concluded that there is significant scientific agreement that the data associating folate intake and reduced risk of neural tube defects support a health claim on this relationship.

The strongest evidence for this relationship comes from the randomized controlled Medical Research Council intervention study (Ref. 14) that showed

that women at risk of a recurrence of a neural tube defect-affected pregnancy who consumed a supplement containing 4 mg (4,000 mcg; 10 times the reference daily intake (RDI) folic acid daily throughout the periconceptional period had a significantly reduced risk of having another child with a neural tube defect. This study demonstrated, for the first time, that there was a significant reduction in recurrence of neural tube defects with high levels of folic acid but not with other vitamins and minerals. This study identified a specific role for folic acid in reducing the risk of recurrence of neural tube defect-affected pregnancies in women with a history of this defect and thus established the scientific basis for a relationship between folate intake and the occurrence of neural tube defects.

In addition, protective effects against occurrence of neural tube defects were found in a Hungarian randomized controlled trial that used a multivitamin/multimineral preparation containing 0.8 mg folic acid daily (Ref. 15). Four of five observational studies have also reported a reduced risk of neural tube defects among women who reported consuming 0.4 to 1.0 mg folate daily from multivitamin supplements (Refs. 10, 11, 13, and 16). Several of these studies (Refs. 11, 13, and 16) have also reported beneficial effects against occurrence of neural tube defects of dietary folate intakes of 100 to 250 mcg or more daily.

Based on its review of all of these studies, the agency has concluded that their results are consistent with the conclusion that folate, at levels attainable from usual diets, may reduce the risk of occurrence of neural tube defects.

The agency agrees that there are still significant gaps in our knowledge about the etiology of neural tube defects; about how folate, either alone or in combination with other nutrients, reduces the risk of neural tube defects; about dose-response relationships between folate intake and reduction in risk of neural tube defect-affected pregnancies; and about the role of other essential nutrients in the etiology of neural tube defects. However, the randomized controlled Medical Research Council trial (Ref. 14) clearly established the specific effectiveness of increased folate intake in reducing the risk of recurrence of some neural tube defects, and the findings of most of the studies cited above (Refs. 9, 10, 11, 13, and 16) are consistent with the conclusions drawn from the results of the Medical Research Council trial.

Because of the consistency between the results of the Medical Research

Council trial and the results of the smaller observational studies, PHS has inferred that folate alone, at levels attainable in usual diets, may reduce the risk of neural tube defects (Ref. 5). FDA participated in the development of the PHS recommendation and noted in the folate health claim proposal (58 FR 53266) that the recommendation evidenced that significant scientific agreement exists regarding the validity of an association between folate intake and risk of neural tube defects.

FDA has therefore concluded, based on its own review of the scientific literature, that there is significant scientific agreement regarding the validity of the relationship, and that the statutory requirements for authorizing a health claim in this topic area have thus been met. Therefore, the agency is adopting § 101.79(c)(2)(i)(A) as proposed.

## 2. Appropriateness of Providing for a Claim

In addition to comments addressing the scientific validity of a health claim on folate and neural tube defects, the agency received comments questioning the advisability of authorizing a claim on this topic.

### a. General comments.

3. Some comments stated that it was advisable to provide for a folate/neural tube defects health claim because such a claim can serve to broaden public knowledge of the relationship between folate and neural tube defects. A comment noted that the folate/neural tube defect claim might be especially beneficial for women who had previously had a child with a neural tube defect. One comment suggested that a health claim for folate and neural tube defects would increase intake of folate by women of childbearing age.

Others expressed concern by noting that consumers will find it difficult to understand the claim and will begin to associate folate-containing foods with an effect on birth defects in general. A comment noted that, given that many occurrences of neural tube defects will not be affected by folate intake, the claim will give a false hope of avoidance of the defect. A comment expressed concern that publication of the claim might cause unnecessary alarm among women who are pregnant. Other comments noted that neural tube defects are not the result of folate deficiency per se or noted the lack of evidence that there is a need in the general U.S. population for an increase in folate intake. Another comment, in considering the agency's proposed model health claims, noted that FDA

was trying to make the food label do more than it can.

Another comment emphasized that the context in which data from the major controlled intervention trial of effects of folic acid at levels approaching those obtainable from diets (i.e., the Hungarian trial; Ref. 15) were obtained (e.g., women who volunteered for the trial gave up drinking and smoking, consumed healthful diets before pregnancy, and in general pursued good health practices in the periconceptional interval) is not the same context in which women in the general population will receive folate.

The agency agrees with the comments above that a health claim for folate and neural tube defects may have an educational benefit and has the potential for increasing folate intake among women in the target population by informing them of the importance of folate intake during their childbearing years. The agency also recognizes the importance of informing women of childbearing age of the need to ensure that their diets include adequate folate throughout this time of their lives and notes that providing information at the point of purchase of food by means of health claims and nutrient content claims can be an effective means of getting the information to consumers and of helping consumers to maintain healthful diets. Given that about half of all pregnancies are unplanned, many women in the general population can benefit from the information provided in the health claim because it will motivate them to increase their folate intake, even if they are not anticipating a pregnancy in the near future.

The agency recognizes that women in the Hungarian trial (Ref. 15) were advised to adopt specific health conscious practices before attempting to become pregnant, and that women in the general population may not adopt such practices before becoming pregnant. The agency notes, however, that there are no data to indicate that the outcome of the Hungarian trial was related to or dependent upon the adoption of those practices, and that all women in the trial were urged to adopt those practices, not only those receiving folate-containing supplements. The agency finds no basis to deny the claim based on such a consideration. In addition, although emphasis is frequently placed upon estimates that about half of all pregnancies in the United States are unplanned, the agency notes that the large numbers of women who do plan their pregnancies (i.e., about 50 percent) may be adopting health-conscious practices before conception and thus may receive folate

in a context similar to that employed in the Hungarian trial.

The agency recognizes that there is the potential for the health claim to be misleading and has addressed that potential by requiring that all claims contain specific information that informs women about the effect that adequate intake of folate during their childbearing years may have on their risk of a specific type of birth defect, without implying that adequate folate intake will provide 100 percent protection against that, or any other, birth defect. The agency recognizes that many nutrients, as well as attention to overall diet and healthful lifestyles, are important for obtaining the best possible outcome of pregnancy and has incorporated these concepts into the language of the health claim.

Specifically, in this health claim regulation, the agency identifies the target population for the claim as women during their childbearing years (§ 101.79(c)(2)(i)(A)); describes the effect of folate intake on the risk of neural tube defects, a very specific type of birth defect (§ 101.79(c)(2)(i)(C)); requires that claims not imply that folate intake is the only recognized risk factor for neural tube defects (§ 101.79(c)(2)(i)(D)); summarizes the significance of appropriate folate intake relative to reduction in risk of neural tube defects in the total dietary context by requiring that claims state that healthful diets are also needed (§ 101.79(c)(2)(i)(H)); and provides for optional (voluntary) identification of a variety of sources of folate in the claim (§ 101.79(c)(3)(vii)). In describing the requirements for foods to bear the claim, the agency has defined characteristics that will qualify a food for bearing the folate/neural tube defect health claim with an eye to ensuring that such foods will be good sources of folate (§ 101.79(c)(2)(ii)(A)).

Provision of such information will assist women in understanding the relationship of folate intake to the risk of neural tube defects and the significance of the information in the context of the total daily diet. Thus, the claim includes facts essential for consumer understanding of the conditions and circumstances under which the claimed effect is more likely to be obtained.

*b. Small size of the population at risk.*

4. Some comments disagreed with the agency's proposal to authorize a health claim for folate and neural tube defects because other authorized claims are different from this one. They pointed out that the folate claim deals with a problem that affects a very small number of people, while other authorized claims deal with reducing

the risk of long-developing conditions affecting very large segments of the population (e.g., calcium and osteoporosis; fat and heart disease). Another comment noted that there have been large unexplained declines in neural tube defects in the United States since the 1930's. Another comment noted that neural tube defects constitute only a small fraction of all birth defects and stated that the proposed claim could lead to a false sense of security regarding protection from risk of all birth defects. Another comment noted that despite their distressful nature, because neural tube defect-affected births are a relatively rare phenomena, they should be attacked at a medical level.

The agency disagrees with comments that it should not authorize a folate/neural tube defect health claim on the basis that the affected population is small in number. The eligibility requirements for a health claim do not limit such claims solely to disease or health-related conditions affecting significant portions of the population. Rather, the general eligibility requirements for health claims require that for a substance to be eligible for a health claim, the substance must be associated with a disease or health-related condition for which the general population or an identified U.S. population subgroup (e.g., the elderly) is at risk (see § 101.14(b)(1)).

As FDA explained in the final rule establishing § 101.14(b)(1) (58 FR 2478 at 2499), the agency will interpret this provision flexibly and will disqualify few claims under it. However, the agency also advised that if the affected population is small in size or is not readily identifiable, information on prevalence in the U.S. population will be a material fact that must be disclosed to avoid misbranding the product.

FDA agrees that the prevalence of pregnancies affected by neural tube defects in the United States is low. However, because it is not currently possible to predict when a pregnancy will be affected, the U.S. subpopulation potentially at risk is large (i.e., women capable of becoming pregnant). The agency, consequently, disagrees that this health claim should not be authorized because a large subpopulation is potentially at risk of a neural tube defect-affected pregnancy.

*c. Potential impact of new data.*

5. Several comments expressed concern that results of research in progress on the potential role of factors other than folate could lead to revisions of the current PHS recommendation that all women consume 0.4 mg of folate daily throughout their childbearing

years to reduce their risk of neural tube birth defects. A comment noted that, based on testimony presented at the April 15 and 16, 1993, meeting of the Folic Acid Subcommittee, data from ongoing studies in South Carolina and Texas will be available soon and should provide information on the effectiveness of folate-containing supplement intervention programs in these areas. Another comment noted that data reported at the recent meeting of the American Public Health Association suggested that while reported intake of folate-containing supplements appeared to be associated with a reduced incidence of neural tube defect-affected pregnancies overall, the association was not statistically significant for Hispanic women who have a higher risk for neural tube defects than many other women.

Some members of the Folic Acid Subcommittee questioned whether new data on vitamin B<sub>12</sub> (summarized in section II.E.6. of this document) should influence the agency's position on the relationship between folate and neural tube defects. Another Folic Acid Subcommittee member stated that regardless of the new findings, the agency should move ahead with the folate/neural tube defect health claim.

The agency is aware that data from several ongoing studies have been discussed at national meetings, but until these data and detailed descriptions of study designs, methodologies, and full results are publicly available, the agency cannot act on them. New data that have become publicly available during this rulemaking are reviewed in Section II.E.6 of this document. The agency notes, however, that the validity of the relationship between folate and neural tube defects has been established by the Medical Research Council trial (Ref. 14). New findings are not likely to detract from the validity of that relationship.

### *C. Issues Regarding the Substance/Disease Relationship That Is the Basis of the Claim*

#### **1. Identifying the Substance (Folic Acid Versus Folate)**

In developing its proposed regulation, the agency considered how best to describe the relationship between folate and neural tube defects. In the proposed statement of the substance/disease relationship (§ 101.79(c)(2)(i)(A)), FDA described the substance that is the subject of the claim as "folate." FDA also used this term in proposed § 101.79(a)(2), (b)(1), (b)(3), (c)(2)(i)(B), (c)(2)(i)(F), (c)(2)(ii)(A), (c)(2)(ii)(B), (c)(2)(iv), (c)(3)(ii), and (d). The agency's use of this term differed from the

wording of the 1990 amendments which required that FDA evaluate the relationship between "folic acid" and neural tube defects.

Based on its review of the available studies, the agency in its October 14, 1993, proposed rule (58 FR 53254 at 53280) described its rationale for broadening the topic by noting that the term "folates" is used broadly to represent the entire group of nutritionally active folate vitamin forms and includes both synthetic folic acid and the folylpolyglutamates that occur naturally in foods.

In reviewing the scientific evidence on the relationship between folate and neural tube defects, the agency noted that some studies reported effects of use of supplements of folic acid in combination with intakes of food folates (Ref. 10), while other studies reported effects of dietary intakes of food folates alone (Refs. 11, 13, and 16). Based on its review of these studies, the agency tentatively concluded that the diet/disease relationship is more accurately described as being related to all of the biologically active vitamin forms of folate rather than just to the synthetic form of the vitamin (i.e., folic acid). Thus, in its review of the substance/disease relationship, FDA considered the effect of all of the nutritionally active forms of this vitamin (i.e., folates) on neural tube defects and not just the effect of the form of the vitamin specified in the 1990 amendments (i.e., folic acid). Use of the term "folate" in proposed § 101.79(a)(2), (b)(1), (b)(3), (c)(2)(i)(B), (c)(2)(i)(F), (c)(2)(ii)(A), (c)(2)(ii)(B), (c)(2)(iv), (c)(3)(ii), and (d) was consistent with the scope of the agency's review.

6. A comment stated that FDA had unjustifiably changed the demonstrated efficacious form of the vitamin from "folic acid" to "dietary folate," and that because dietary food folate has not been demonstrated to reduce the incidence of neural tube defects, such a change is not justified. Several comments stated that FDA, in its health claims proceedings, had departed from the PHS recommendation, which uses the term "folic acid" in its title and in describing dietary change associated with reduced risk of neural tube defects, and that FDA, instead, concentrated inappropriately on food folate.

FDA does not agree with these comments and concludes that it was justified in expressing the food substance/disease relationship as "folate and neural tube defects" rather than as "folic acid and neural tube defects." FDA also disagrees with the comments that folic acid is the only substance that was appropriately the subject of FDA's

review, and that dietary food folate has not been demonstrated to reduce the incidence of neural tube defects.

a. *Efficacy of food folate.* In reviewing the scientific evidence on the relationship between folate and neural tube defects, the agency noted that one study attributed all observed effects to consumption of dietary supplements of undefined composition without quantifying contribution of folate either from the supplements or from food (Ref. 10), while other studies attempted to specifically quantify intakes of folate from food as well as from dietary supplements (Refs. 11, 13, and 16).

Some studies reported protective effects of use of supplements containing folic acid in combination with intakes of food folates (Refs. 11, 13, and 16), while other studies reported protective effects from dietary improvement in general (Ref. 17) or from intakes of food folates alone (i.e., without supplement use) (Refs. 11 and 13).

Milunsky et al. (Ref. 11), Bower and Stanley (Ref. 16), and Werler et al. (Ref. 13) presented data on the relationship of dietary folate to risk of neural tube defects among nonusers of dietary supplements. Each of these studies found reduced risk of neural tube defects associated with increasing dietary intake of food folate. In the prospective study of Milunsky et al. (Ref. 11), the relative risk of neural tube defects was 0.42 for those women ingesting more than 100 mcg folate per day compared with those ingesting less than 100 mcg folate per day. Bower and Stanley (Ref. 16), in a study in Western Australia, found reduced risk of neural tube defects among women consuming more than 240 mcg food folate per day versus community controls. Werler et al. (Ref. 13) reported a significant trend of reduced occurrence of neural tube defects with increasing dietary food folate.

Laurence et al. (Ref. 17) performed a trial of dietary education without prescribing supplements and found that improvement in women's diets from "poor" to "good" led to a 50 percent reduction in recurrence of neural tube defects in women at high risk of this complication. Dietary improvement is assumed to increase intake of folate and many other nutrients by unspecified amounts. Specifically, these authors reported no cases of neural tube defects among women who were judged to have eaten "good" or "fair" diets (Ref. 17). All recurrences occurred among the 30 of 186 women who were judged to have eaten "poor" diets. "Poor" diets were defined as those considered to be deficient in first-class protein, usually no fruits and vegetables, and generally

with excessive amounts of carbohydrates. "Good" diets were defined as those providing good intakes of all essential foods, including protein, and with no excessive amounts of refined carbohydrates, sweets, and soft drinks (see 58 FR 53253, October 14, 1993).

The studies of Milunsky et al. (Ref. 11), Bower and Stanley (Ref. 16), Werler et al. (Ref. 13), and Laurence et al. (Ref. 17) have all demonstrated that food folates provide protective effects against risk of neural tube defects.

b. *Interchangeability of the terms "folate" and "folic acid" in common usage and in nutrition labeling.* FDA notes that, in common usage, the terms "folic acid" and "folate" are frequently used interchangeably to describe the biologically active forms of the vitamin. Folate is ubiquitous in nature, being present in nearly all natural foods (Ref. 18), and occurring in a wide range of forms (Ref. 19). Human nutritional requirements for folate can be met by a variety of naturally occurring forms of the vitamin from many sources as well as by pteroylglutamic acid, the form of the vitamin added as a fortificant to breakfast cereals and other foods, and the form present in dietary supplements.

In nutrition labeling, "folic acid," "folate," and "folacin" are allowable synonyms (§ 101.9(c)(8)(iv) and (c)(7)(iv)). All of these terms provide a way to describe the nutritional value of folate vitamin forms, although the term "folacin" is now rarely used.

c. *Interchangeability of the terms "folate" and "folic acid" in the PHS recommendation.* FDA disagrees that the PHS statement emphasizes synthetic folic acid, the form of the vitamin used as a fortificant in conventional foods and in dietary supplements. In point of fact, the PHS statement, consistent with lay information and with nutrition labeling regulations, uses the terms "folic acid" and "folate" interchangeably (Ref. 5). For example, the PHS recommendation states that "folate intake  $\geq$  0.4 mg/day can be obtained from the diet through careful selection of foods," that improvement in dietary habits is one potential approach "for the delivery of folic acid to the general population in the dosage recommended," and that "women should be careful to keep their total daily folate consumption at < 1 mg per day" (Ref. 5).

That some ambiguity with respect to use of the terms "folic acid" and "folate" was present in the PHS recommendation was recognized during finalization of the recommendation at a CDC-sponsored meeting held in Atlanta

on July 27, 1992. At that meeting, CDC staff noted that the ambiguity was deliberate (Ref. 20):

INVITED SPEAKER WALD: There is an ambiguity here over whether it's total or extra, unless you have a particularly kind of astute legal perspective on this. \* \* \* I have a question, though. Was the ambiguity deliberate?

CDC's ERICKSON: Yes.

INVITED SPEAKER WALD: You see, I think I would have probably inserted the same ambiguity myself. Because the intention is to get something going. \* \* \* And one has the 0.4 mg figure from the previous RDA \* \* \* at least that is a psychological fixing point.

Thus, there was some ambiguity in the PHS recommendation from the time of its development, and the recommendation does not identify synthetic folic acid as the sole active form of the vitamin.

d. *Conclusion.* Based on its review of the available studies, the agency tentatively concluded in the proposed rule that the food substance/disease relationship is most accurately expressed as "folate and neural tube defects" rather than as "folic acid and neural tube defects" because the term "folate" encompasses all forms of the vitamin from any source. In addition, at intakes attainable from usual diets, both folate from foods and folic acid from fortified foods or dietary supplements are converted into the same functional, metabolically active, reduced coenzyme vitamin forms in the body (Ref. 19). Thus, nutritional requirements are met by a variety of forms of folate, and, with respect to reduction in risk of neural tube defects, the utility of increased folate intake, whether achieved through improved food choices or through use of dietary supplements, has been shown.

The comments summarized above do not provide a basis for the agency to change the relationship statement because they are inconsistent with the scientific data, and they do not provide data that demonstrate that "folic acid" performs nutritional functions different from those performed by naturally occurring food folates. Thus, making a distinction between "folate" and "folic acid" when all forms of the vitamin are capable of conversion to active vitamin coenzymes and metabolic function is artificial and inappropriate.

Therefore, in § 101.79, FDA is authorizing a health claim on labels and in labeling of conventional foods and dietary supplements about the relationship between folate and neural tube defects in women of childbearing age. The agency is retaining this terminology throughout the codified language. However, § 101.79(c)(2)(i)(B) states that any one of several synonyms

may be used, including "folic acid" and "folate," when specifying the nutrient in a health claim.

FDA notes that in proposed § 101.79(c)(2)(i)(F), the term "folic acid" was used instead of the intended term "folate," which was otherwise consistently used throughout the proposed codified language. FDA is correcting this terminology in the final codified language, which for other reasons described in this preamble is redesignated as § 101.79(c)(2)(i)(E).

## 2. Issues of Source and Amount

In § 101.79(c)(2)(i)(H), the agency proposed to prohibit statements in the health claim that a specified amount of folate (e.g., 400 mcg (100 percent of the Daily Value (DV)) in a dietary supplement) is more effective in reducing the risk of neural tube defects than a lower amount (e.g., 100 mcg (25 percent of the DV) in a breakfast cereal or from diets rich in fruits and vegetables). The agency proposed this limitation because it is consistent with scientific data showing that reduced risk of neural tube defects has been associated with general dietary improvement, which is assumed to increase folate intake by unspecified amounts. In response to this proposed limitation, the agency received comments addressing the separate issues of source of folate and amount of folate.

### a. Source.

7. Several comments agreed with the agency's proposal, stating that health claims should not contain statements that adequate diets cannot provide sufficient folate, or that only fortified foods or supplements can provide adequate folate. Other comments disagreed, stating that FDA should require claims to state that the evidence that folate reduces the risk of neural tube defects is stronger for supplements than for food. Other comments stated that evidence that folate-rich diets reduce the risk of neural tube defects is only suggestive, while evidence that folic acid containing-supplements reduce the risk of neural tube defects is conclusive.

The agency agrees with comments that health claims should not contain statements that diets cannot provide sufficient folate to affect the risk of a neural tube defect because such statements are inconsistent with the available scientific evidence.

The studies of Milunsky et al. (Ref. 11), Bower and Stanley (Ref. 16), Werler et al. (Ref. 13), and Laurence et al. (Ref. 17) were summarized in response to comment 6, above. Milunsky et al. (Ref.

11), Bower and Stanley (Ref. 16), and Werler et al. (Ref. 13) all presented data on the relationship of dietary folate to risk of neural tube defects among nonusers of dietary supplements. Each of these studies found reduced risk of neural tube defects associated with increasing intakes of dietary folate. Laurence et al. (Ref. 17) found fairly strong protection against recurrence of neural tube defects associated with improvement in overall diets.

FDA concludes, based on its review of the scientific literature, that the proposed limitation in § 101.79 on statements that specific sources are superior to others is appropriate because the scientific literature does not support the superiority of any one source over others. As noted above, both folate from conventional foods and folic acid from fortified foods or dietary supplements are converted into functional, metabolically active coenzyme forms for use in the body (Ref. 19). Thus, in the absence of the limitation, manufacturers would be free to put statements that would be false and misleading in their labeling. The agency's conclusion is consistent with PHS's recommendation that advises that careful selection of foods is one means by which women can increase their folate intakes.

**b. Amount.**

8. Several comments agreed with the agency that the claim should not state that a specific amount of folate is more effective than another amount. Several comments noted that dose/response data to justify such statements do not exist, and that scientists do not yet know the requisite folate level that will protect the fetus from a neural tube defect. Other comments disagreed, stating that claims should state that experts recommend 400 mcg per day or 100 percent of the DV when referring to adequate amounts of folate. Another comment stated that while the 400 mcg level is admittedly imprecise, it is the recommendation of PHS. Another comment stated that consumers need to be reminded that a reduction in neural tube defects will only occur if all women consume 400 mcg folate per day throughout their childbearing years.

The agency agrees with comments that dose/response data are insufficient to provide a basis for stating that a specific amount of folate is more effective than another amount. The quantitative results from the studies of Milunsky et al. (Ref. 11), Bower and Stanley (Ref. 16), and Werler et al. (Ref. 13) suggest that amounts *lower* than the current recommendation of 400 mcg may be protective.

After reviewing the comments above and the available scientific literature,

FDA concludes that the comments do not provide a basis for the agency to change its position regarding prohibition of statements in the claim that imply that specific amounts of folate are superior to other amounts because such statements are inconsistent with the scientific data. FDA's conclusion is consistent with information provided in the PHS recommendation that states that amounts of folate lower than 400 mcg may reduce the risk of neural tube defects, and that additional research is needed to establish the minimum effective dose (Ref. 5). Again, a contrary position by the agency would permit false statements to appear on the label.

In the final codified language, the agency is redesignating proposed § 101.79(c)(2)(i)(H) as § 101.79(c)(2)(i)(G) and, for the reasons stated above, is prohibiting in § 101.79(c)(2)(i)(G) claims that a specified amount of folate per serving from one source is more effective in reducing the risk of neural tube defects than a lower amount per serving from another source.

**c. Restriction of claims to specific products.**

9. Several comments stated that the health claim should be limited to supplements containing 400 or 800 mcg of folate or limited to dietary supplements or breakfast cereals containing 400 mcg of folate. Other comments stated that health claims should not be allowed for naturally occurring food folates. Another comment stated that to allow health claims solely on supplements or fortified foods would undermine the need for women to learn to eat more healthfully and to obtain a full array of nutrients found in a balanced diet.

The agency disagrees with comments that recommended that it limit claims to dietary supplements or to dietary supplements and fortified breakfast cereals that contain 400 mcg or more of folate. The agency's review of the scientific literature, summarized in response to comments 6 to 8 above, provides no basis for making a distinction in source or in amount between folate from conventional foods and folic acid from dietary supplements or fortified cereals because the available evidence shows that increased folate intake, rather than the source of the folate, is what is of importance in reducing the risk of neural tube defects (Ref. 5). Increasing total folate intake among women of childbearing age, rather than emphasis on one source versus another, is what is of importance. This conclusion is consistent with PHS's recommendation, which states that improvement in dietary habits and

use of dietary supplements are both appropriate approaches by which women may increase their folate intake.

**d. Target intake goal.** The agency proposed in § 101.79(c)(3)(iv) to include as optional information in the health claim a statement that the DV level of 400 mcg of folate is the target intake goal.

10. Several comments stated that all health claims should refer to the likely effectiveness of 400 mcg of folate, or that claims should be required to state that experts recommend 400 mcg per day. Other comments stated that 400 mcg is the PHS recommendation, and without this information, women may assume that lower amounts are adequate.

The agency disagrees with these comments. FDA chose not to propose to require that claims identify 400 mcg as the target intake goal because it tentatively concluded that there is uncertainty as to the optimal intake of folate with respect to reduction in risk of neural tube defects (Ref. 5). As noted above, several studies (Refs. 11 and 13) have found reductions in risk of neural tube defect-affected pregnancies at folate intakes below 400 mcg per day. None of the comments provided evidence that showed that these findings were not valid. Thus, FDA concludes that a requirement that claims state that women must consume 400 mcg folate per day to achieve a reduction in risk of a neural tube defect-affected pregnancy would be inconsistent with the available scientific data.

However, because 400 mcg is the reference daily intake (RDI), because PHS recommends a 400 mcg/day intake, and because the Folic Acid Subcommittee supported the 400 mcg/day intake goal, the agency has concluded that it may be helpful to some consumers if the health claim were to include information that the RDI of 400 mcg per day is the target intake goal. Therefore, FDA is adopting § 101.79(c)(3)(iv) to allow for optional inclusion of this information, with the target intake goal (400 mcg; 0.4 mg) expressed as 100 percent DV. Claims may identify 100 percent of the DV (400 mcg folate) as the target intake goal and may state the PHS recommended daily intake (400 mcg folate, 0.4 mg).

**3. Focusing on the Periconceptional Interval**

In proposed § 101.79(a)(1), the agency defined neural tube defects as serious birth defects of the brain or spinal cord. The agency noted that these defects result from a failure of the covering of the brain or spinal cord to close during

early embryonic development and further noted that, because the neural tube forms and closes during early pregnancy, the defect may occur before a woman realizes that she is pregnant. In proposed § 101.79(a)(2), the agency described the relationship between adequate folate intake and reduced risk of a neural tube defect-affected pregnancy and summarized the studies whose results provide the basis for the health claim.

11. A number of comments stated that studies have shown that folic acid added to the diet before pregnancy reduces the risk of neural tube defects, and that the relationship statement should be corrected to reflect this fact.

The agency agrees that the studies that provide the basis for the relationship between folate and neural tube defects focused on improved folate nutriture before conception and continuing into early pregnancy. Therefore, the agency is modifying several of the statements in § 101.79(a)(2) to more precisely describe the results of these studies. Specifically, FDA is modifying the second sentence of § 101.79(a)(2) to state that in the studies described, folic acid was consumed daily "before conception and continuing into early pregnancy \* \* \*," and the fourth sentence to state that the study involved reported periconceptional use of multivitamins that contained folic acid.

12. A comment suggested that claims be allowed to be more precise in describing the period during which adequate folate is needed. The comment noted that the statement relating to daily consumption of folate throughout the childbearing years implies that body folate stores must be built up over decades, while studies have shown that it is sufficient to consume folate during the weeks before the neural tube closes. The comment proposed that a statement that women who consume adequate amounts of folate during the month before and after becoming pregnant may reduce their risk of a neural tube defect would convey this information. Another comment criticized the model health claims provided by the agency because they failed to alert women to the critical periconceptional period.

The agency recognizes that the scientific data support the need for specific attention to folate intake in the periconceptional interval and has modified § 101.79(a)(2) to reflect this fact by specifically mentioning periconceptional use.

The agency notes that one of the purposes of health claims is to assist women in recognizing the importance of healthful diets, including adequate

folate nutriture throughout their childbearing years (see H. Rept. 101–538, 101st Cong., 2d Sess. 9–10 (1990)). Given that about 50 percent of pregnancies are unplanned, and that many women may not recognize that they are pregnant until after the critical period of neural tube closure, it is important for women to maintain healthful diets throughout their childbearing years. While some women who plan their pregnancies might benefit from the more specific information suggested in the comment, the agency concludes that the more general wording in the model claims will reach a wider group of women and provide them with useful and important information.

FDA is adopting § 101.79(c)(3)(ii), which states that health claims may include statements from paragraphs § 101.79 (a) and (b). Through the use of statements derived from § 101.79(a)(2), manufacturers will be able to provide information that alerts women to the importance of the periconceptional period.

#### 4. "Will Reduce" Versus "May Reduce"

13. One comment stated that proposed § 101.79(a)(2), which stated that available data show that diets adequate in folate may reduce the risk of neural tube defects, was misleading and recommended that this section be reworded to state that "studies have shown that folic acid added to the diet before a pregnancy occurs will reduce the risk of neural tube defects."

The agency disagrees with the assertion that adequate folate intake *will* reduce the risk of neural tube defects. The available data show that in an area of low prevalence of neural tube defects, folate intake from dietary supplements or from fortified cereals was not associated with reduced risk of neural tube defects (Ref. 12). The agency did not receive any data or information challenging this data.

The agency notes that use of the term "will reduce" is overly promissory to the individual and is misleading because it is not consistent with the available data. Prevalence rates for neural tube defects vary with a wide range of factors including genetics, socioeconomic status, maternal health, and race. The agency has discussed the multifactorial nature of neural tube defects (and will do so again below (see comment 36 of this document)). It has concluded that claims need to reflect this aspect of the nature of these defects because folate intake is not the only risk factor for them. Use of the term "will reduce" in the claim is not consistent with the multifactorial nature of neural

tube defects. Thus, FDA finds no basis to change the wording of § 101.79(a)(2), and it is including the sentence "The available data show that diets adequate in folate may reduce the risk of neural tube defects" in the final regulation without change.

#### 5. Need for Healthful Diets

14. Some members of the Folic Acid Subcommittee expressed concern about a single nutrient approach to the problem of neural tube defects because nutrients function together in the body. Another comment felt that a health claim for folic acid could be misinterpreted to mean that folic acid could prevent all birth defects. One comment noted that, because nutrients function synergistically in the body, increasing a single nutrient is unwise. Another comment stated that by focusing on the relationship between a single nutrient and a single outcome, opportunities to improve overall health are missed. Another comment expressed concern about singling out one vitamin for a health claim when the major sources of the vitamin (e.g., fruits and vegetables) are being promoted for good health. Other comments noted that in pregnancy it is the total diet, not a single nutrient, that is related to health outcome.

The agency agrees with the comments that expressed concern about the problems in focusing on a single-nutrient, particularly in women of childbearing age. Many nutrients affect healthy pregnancy, and the claim should not lead women to focus undue attention on one nutrient, or on a single dietary factor, instead of on overall healthful diets and health conscious behaviors.

In addition, because healthy pregnancies and good pregnancy outcomes are dependent upon an overall good diet, adequate in protein, vitamins and minerals, and many other nutrients, women should not be misled into believing that folate is the only nutrient about which they need to be concerned in preparing for a pregnancy. With respect to neural tube defects, FDA in its proposed rule (58 FR 53254) reviewed evidence that nutrients other than folate (e.g., methionine, vitamin B<sub>12</sub>, pantothenic acid) have roles in reducing the risk of neural tube defects, and additional evidence is summarized in section II.E.6. of this document. Thus, normal fetal development requires many nutrients in addition to the nutrient that is the subject of the health claim.

Based on these considerations, the agency has concluded that information regarding overall improvement in a woman's diet and nutrition in the

periconceptional interval, as well as throughout her childbearing years, is of considerable importance because pregnancy outcome depends upon adequate intakes of a wide range of nutrients. This concern needs to be balanced against the fact that the available evidence provides the basis for significant scientific agreement that dietary intakes of folate may reduce the risk of neural tube defect-affected pregnancies.

Therefore, in response to these comments, FDA is including in § 101.79(c)(2)(i)(H) in the final regulation a requirement that the claim state that folate needs to be consumed as part of a healthy diet. This requirement will ensure that, while highlighting the role of adequate folate intake, the health claim will not cause women to place undue emphasis on consumption of this nutrient. Thus, this information is necessary to ensure that the claim is properly balanced.

#### *D. Requirements for Foods Bearing the Claim*

##### *1. Qualifying Amounts*

In § 101.79(c)(2)(ii)(A), FDA proposed that the food or dietary supplement meet or exceed the requirements for a "good source" of folate as defined in § 101.54 (i.e., containing  $\geq 10$  percent of the RDI). In proposing this eligibility requirement, FDA considered that folate is ubiquitously distributed in the U.S. food supply. While a number of foods (e.g., some legumes, okra, broccoli, spinach, turnip greens, asparagus, Brussels sprouts, endive, lentils) contain more than 80 mcg of folate/serving (the amount that is greater than or equal to 20 percent of the RDI (i.e., that amount that would be required for a claim of a "rich" source)), the great majority of foods contain folate at lower levels. For example, oranges, grapefruit, many berries, peas, many vegetable juices, beets, and parsnips contain folate at levels of 40 to 80 mcg/serving (i.e., at or above 10 percent of the RDI or at levels that meet the requirement of a claim of a "good" source) (Ref. 22).

##### *a. General comments.*

15. Many comments and the Folic Acid Subcommittee and Food Advisory Committee were generally satisfied with the eligibility requirements and supported FDA's proposal to allow claims on foods that were at least a good source of folate. These comments supported the criterion because it would accommodate a wide variety of fruits and vegetables that would be excluded if the eligibility requirement was set at a higher level. One comment, however, suggested that the proposed amount was

too high and might exclude some commonly consumed foods such as peas.

A third group of comments thought that the proposed amount was too low. Some of the comments said that claims should not be permitted unless the food provides at least 20 percent of the RDI (i.e., 80 mcg folate/serving), arguing that it was poor policy to make exception to the general health claims requirements regulations, and that if the goal is to maximize intake of folate, then 20 percent of the RDI should be the minimum amount allowed for the claim. Others felt strongly that the claim should be limited to those foods or supplements that provide 100 percent of the RDI per serving or per dose.

The agency is concerned that if it required (in accord with § 101.14(d)(2)(vii)) that the food contain 20 percent or more of the RDI for folate (i.e., 80 mcg or more folate per reference amount customarily consumed; an amount sufficient to qualify for a "high" or "excellent source of" nutrient content claim) to bear a health claim, many good food sources of folate would not qualify without fortification.

One of Congress' purposes in providing for health claims was to enable Americans to maintain a balanced and healthful diet (H. Rept. 101-538, supra, pp. 9-10). Given this fact, and given that the evidence demonstrates that the risk of neural tube defects can be affected by consuming foods that, while good sources of this nutrient, do not provide the high level that is provided by supplements and highly fortified foods (see Refs. 11, 13, 16, and 17), FDA concludes that it would not be consistent with the intent of the 1990 amendments to set requirements that would limit eligibility to bear a health claim to the foods that are high in folate.

Use of a qualifying criterion for the health claim that is consistent with the "good source" definition (i.e., 10 to 19 percent of the DV; 40 to 76 mcg folate/serving) provides for an amount of the nutrient that allows a wide variety of fruits, vegetables, and whole grain products to qualify to bear the health claim, is consistent with current Federal guidelines for general dietary patterns, and yet is still likely to result in a daily dietary intake of folate that the data show may reduce the risk of neural tube defects. For example, current Federal dietary guidelines recommend five or more servings of fruits and vegetables and six or more servings of grain products per day. Consumption of fruits, vegetables, and grain products in the recommended amounts would likely result in daily intakes of folate of 0.4 mg

(400 mcg) or more, even though individually many of the foods consumed contain less than 20 percent of the RDI for folate per reference serving (Ref. 22).

Accordingly, FDA is adopting § 101.79(c)(2)(ii)(A), which provides that conventional foods and dietary supplements can bear a folate/neural tube defect health claim if they contain 10 percent or more of the RDI for folate per reference amount customarily consumed (i.e., meet the definition for a "good source" claim in § 101.54 (21 CFR 101.54)). The availability of the claim for a wide variety of products will provide flexibility to women in deciding how to individually achieve the target intake by selecting from among foods that naturally contain folate, dietary supplements, and highly fortified foods.

##### *b. Higher qualifying amounts for dietary supplements than for foods.*

16. Several comments stated that to qualify to bear the claim, each food should provide at least 25 percent of the RDI, and each supplement should provide 100 percent of the RDI. However, these comments did not provide any support for the levels that they suggested or for why supplements should have to have a higher level of the nutrient than a conventional food.

Having dealt with the level necessary to qualify to bear the claim in response to the previous comment, the agency will deal here with the question of whether, to qualify for a claim, dietary supplements should be required to provide more folate than foods. The agency concludes that there is no reason why they should. In response to comment 7 of this document, the agency concluded that the available scientific evidence establishes that sources of folate are equivalent in their ability to provide folate. Thus, there is no basis for requiring that either dietary supplements or conventional foods provide more than 10 percent of the RDI for folate per reference amount customarily consumed to qualify for the claim.

##### *2. Disintegration and Dissolution of Dietary Supplements*

FDA proposed in § 101.79(c)(2)(ii)(C) to disqualify dietary supplements from bearing a health claim if they fail to meet the United States Pharmacopeia (USP) standards for disintegration and dissolution. The agency tentatively concluded that the benefits of folate intake from food and dietary supplements can only be obtained if the folate is available for absorption and metabolism by the body. The agency noted that a dietary supplement that does not disintegrate and dissolve



clearly does not provide the nutrient in an assimilable form, and that a claim for such a supplement would be misleading because the supplement would not provide the nutrient that is the subject of the health claim (58 FR 58283).

17. Several comments agreed with the agency's proposed requirement and urged the agency to require all dietary supplements to meet such quality standards. Another comment proposed that the agency use the USP standards that are currently under development, and that the dissolution requirement become effective when the USP proposal becomes effective. The USP commented and proposed wording for use in § 101.79(c)(2)(ii)(C): "Folic acid present in dietary supplement dosage forms (e.g., tablets, capsules) shall meet the requirements of the United States Pharmacopeia as defined in Section 201(j) of the act."

Another comment stated that in making this proposed requirement effective for dietary supplements, the agency would accord the same claim to foods (i.e., conventional foods) without similar requirements for bioavailability, and that excluding foods from this requirement was scientifically unjustified. The comment did not identify conventional foods from which folate had been demonstrated to be unavailable or elaborate on the concern.

The agency proposed that dietary supplements meet USP standards for dissolution and disintegration, and that bioavailability under conditions of use stated on the label be shown *only* if there are no applicable USP standards for disintegration and dissolution. Thus, the agency proposed that a demonstration of bioavailability would be required *only* if there were no USP method available to check for dissolution and disintegration.

The comment that stated that in making the requirement proposed in § 101.79(c)(2)(ii)(C) effective for dietary supplements, the agency would accord the same claim to conventional foods without similar requirements, may have misread the agency's proposed requirement. "Bioavailability" includes, but is not limited to, dissolution and disintegration. Dissolution and disintegration are necessary preconditions for absorption and subsequent metabolism. Digestive processes ensure that conventional foods are digested, and that components are liberated for absorption. With respect to the bioavailability of folate from conventional foods, the agency is aware that the bioavailability of folate varies widely but is not aware of any foods from which folate has been shown to be unavailable.

However, dietary supplements, including folate-containing supplements, can be manufactured in a manner that prevents dissolution and disintegration (e.g., extremely compressed preparations), and the digestive processes may be insufficient to ensure the liberation of the components for absorption. The components of such a supplement would not be available for absorption and utilization by the body. A claim on a dietary supplement that does not disintegrate or dissolve would be misleading because the supplement would not meet the preconditions necessary to ensure that the nutrient that is the subject of the claim is available for absorption.

The agency did not receive other comments contending that dietary supplements should not meet USP standards for disintegration and dissolution, or that bioavailability should not be demonstrated when applicable USP disintegration and dissolution standards are not available. The agency is adopting § 101.79(c)(2)(ii)(C) as proposed and is redesignating it as § 101.79(c)(2)(ii)(B).

### 3. No Health Claim on Foods or Supplements Containing More Than 100 Percent of the RDI for Preformed Vitamin A or Vitamin D

In § 101.79(c)(2)(iii), FDA proposed that a health claim for folate and neural tube defects be prohibited on conventional foods and on dietary supplements that contain more than 100 percent of the RDI for vitamin A as retinol or preformed vitamin A or vitamin D per serving or per unit. The agency proposed this limitation because of the recognized toxicity of high intakes of these vitamins for the fetus and the teratogenic effects of these nutrients at levels not greatly in excess of the RDI.

18. Several comments agreed with FDA's proposal, noting that many dietary supplements currently contain more than 100 percent of the RDI for vitamin A, and that such levels are unnecessary and potentially harmful. Another comment misread the proposed requirement regarding vitamin A and noted that since manufacturers were now increasing the  $\beta$ -carotene content of supplements because of health benefits, these supplements should not be excluded from carrying a folate/neural tube defect claim because of their high  $\beta$ -carotene content.

The agency is aware that folate is often combined with other nutrients, particularly vitamins and minerals, in dietary supplement formulations or in highly fortified foods. In light of the

expectation that the presence of a health claim on the label of such products is likely to result in increased intake of these products, FDA is concerned that some consumers may try to increase their folate intake by consuming multiple doses of dietary supplements or multiple servings of highly fortified foods. The agency was concerned that, for some fortified foods and dietary supplements that contain both folate and preformed vitamin A or vitamin D, consumers could be exposed to excessive vitamin A or vitamin D intakes in their attempts to obtain increased amounts of folate. The agency, however, did not propose similar requirements for  $\beta$ -carotene because the agency is not aware of data on potential teratogenic or other adverse effects of  $\beta$ -carotene on the fetus.

This limitation is consistent with other recent recommendations. In 1991, the CDC recommendation for increased intake of folate by women with a history of a neural tube defect-affected pregnancy (Ref. 23) warned against overconsumption of multivitamins because of the potential for excessive intakes of vitamins A and D from such preparations and the known adverse effects of these vitamins on the health of the fetus. In addition, recent recommendations in Canada for women of childbearing age regarding folic acid and neural tube defects recognized the teratogenicity of high levels of vitamin A and cautioned against excessive intakes of this nutrient (Ref. 24).

With the exception of the comment regarding  $\beta$ -carotene discussed above, the agency received no comments objecting to this requirement. Thus, the agency is adopting § 101.79(c)(2)(iii) as proposed. The agency advises that the limitation contained in this provision pertains only to conventional foods or to dietary supplements that contain more than 100 percent of the RDI for vitamin A as retinol or preformed vitamin A or vitamin D.

## E. Label Information

### 1. Mandatory Nutrition Labeling

In § 101.79(c)(2)(iv), FDA proposed to require that the nutrition label of conventional foods or dietary supplements bearing the folate/neural tube defect health claim provide information about the amount of folate in the food or dietary supplement. This proposed requirement is consistent with § 101.9(c)(8)(ii) (21 CFR 101.9(c)(8)(ii)), which states that the declaration of vitamins and minerals on the nutrition label shall include any of the vitamins



and minerals listed in § 101.9(c)(8)(iv) when a claim is made about them.

19. One comment agreed with the proposed requirement for mandatory nutrition labeling on products bearing the folate/neural tube defects health claim. Another comment noted that use of multiple terms such as "micrograms," "milligrams," etc., would probably confuse lay persons.

The agency agrees with the comments and is adopting, with the modifications noted below, the requirement in § 101.79(c)(2)(iv) that products bearing the health claim include in the nutrition labeling information about the amount of folate in the food.

FDA adopted the 1980 Recommended Dietary Allowance (RDA) values as RDI values, with folate values expressed on the label in milligrams (mg) and percent of the DV (58 FR 2206, January 6, 1993). In the Federal Register of January 4, 1994 (59 FR 427 at 431), FDA proposed to amend § 101.9 by revising paragraph (c)(8)(iv) to state, among other things, the RDI for folate in micrograms (i.e., 400 micrograms; 400 mcg). The agency stated that changing the current unit of measure for folate will facilitate consumer comprehension of quantitative nutrient information because consumers are more familiar with this nutrient being expressed in microgram units.

In § 101.79(c)(2)(i)(F) and (c)(3)(iv), FDA has modified the codified language so that all references to folate intake in the health claim will be required to be expressed as percent DV with the option of adding the microgram equivalent in parentheses. That is, values for folate will be expressed as percent of the DV (i.e., the percent of the RDI as established in § 101.9(c)(8)(iv)). FDA has modified the codified language in § 101.79(c)(2)(i)(F) so that reference to the safe upper limit of daily folate intake in the health claim will also be required to be expressed as percent DV with the option of adding the microgram equivalent in parentheses (see comment 32 of this document). Thus, in response to the comment's concern about the confusion that would result if multiple terms are used to describe the level of folate, FDA has modified the regulations to provide for consistent terminology.

## 2. Identifying the Nutrient

In proposed § 101.79(c)(2)(i)(B), FDA considered the use of synonyms for "folate" and the need to aid consumers in understanding this nutrient. The agency provided for the use of synonyms and for additional description of this term through phrases such as "folate," "folic acid," "folacin,"

"folate, a B vitamin," "folic acid, a B vitamin," and "folacin, a B vitamin."

20. Several comments agreed that the agency's proposed synonyms are appropriate. Other comments urged that a single term, for example, "folic acid," "folic acid, a B vitamin," "folate," or "folate, a B vitamin," be used throughout all claims. Other comments agreed with the use of the agency's proposed synonyms to encourage the consumption of healthy diets but recommended that claims be worded in such a way as to demonstrate that "folic acid" is the effective form. Several comments disagreed with use of the term "folacin," noting that it was rarely used.

The agency notes that the descriptive term "a B vitamin" in conjunction with "folate," "folacin," or "folic acid" is commonly used in lay information for consumers and may be useful for consumers in indicating the nutritive function of folate as a vitamin. FDA is thus retaining the provision for its optional use in § 101.79(c)(2)(i)(B).

FDA recognizes that current regulations for nutrition labeling in §§ 101.9 and 101.36 do not include the term "folic acid" as an allowable synonym for folate. This omission was an oversight when the agency amended § 101.9 (58 FR 2079 at 2178, January 6, 1993), and when it promulgated § 101.36 (59 FR 373, January 4, 1994). Before it was amended, § 101.9 had listed folic acid as the preferred term, with folacin as an allowable parenthetical synonym. When it proposed amendments to § 101.9 in 1990 (55 FR 29847, July 19, 1990), the agency explained why the term "folate" was preferable to "folacin". However, an explanation for use of "folic acid" was inadvertently omitted in that document, as was inclusion of the term "folic acid" as an allowable synonym.

The agency has advised firms that it would have no objection to the use of the term "folic acid" in nutrition labeling. In light of common usage and FDA policy, and for consistency among nutrition labeling and health claim regulations, the agency is making a technical amendment to §§ 101.9 and 101.36 in this final rule to include "folic acid" as an allowable synonym for folate.

The agency notes that, as discussed in comment 6, above, the terms "folic acid" and "folate" are both used in the PHS recommendation (Ref. 5). By allowing the use of these terms, the PHS recommendation can be quoted directly on the label if all other requirements for the health claim are met. The inappropriateness of limiting the term to "folic acid" to describe the relationship

has been discussed in response to comment 6 of this document. Therefore, FDA is adopting § 101.79(c)(2)(i)(B) as proposed.

## 3. Identifying Diets Adequate in Folate

In § 101.79(c)(2)(ii)(B), the agency proposed to require that health claims relating folate to neural tube defects identify sources of folate by stating that adequate amounts of folate may be obtained by making specific dietary choices of folate-rich foods, as well as through use of dietary supplements or fortified breakfast cereals. The purpose of this proposed requirement was to assist women in obtaining adequate amounts of folate in their diets by providing information on sources of folate. In proposed § 101.79(c)(2)(ii)(B), the agency provided examples of the types of phrases that could be used to meet this requirement (e.g., "Adequate amounts of folate, a B vitamin, can be obtained from diets rich in fruits, dark green leafy vegetables and legumes, enriched grain products, fortified cereals, or from dietary supplements").

21. Many comments agreed with the proposal to require statements that dietary sources such as fruits, vegetables, and grains may contribute folate to the diet, although some comments disagreed with providing specific details, such as recommended numbers of servings. Other comments supported the agency's proposed approach, emphasizing that the health claim must help consumers understand that, in pregnancy, it is the total diet, not a single food, that is related to health outcome, and that there is good evidence for dietary claims regarding increased folate intake and reduced risk of neural tube defects. Another comment stated that health claims should not reveal a bias against food forms, fortificants, or dietary supplements.

Other comments disagreed with the proposal to identify healthful dietary patterns on the basis that many women will not change their eating habits, and that it is therefore important to point out the importance of use of dietary supplements. Other comments noted that the statements regarding beneficial diets were overly focused on food and should be made optional, that adding dietary information to the health claim reduces its educational effectiveness, and that inclusion of such information was neither required by law nor consistent with other authorized health claims such as that for calcium and osteoporosis. Several comments recommended that statements regarding diets adequate in folate be made optional because such information is

better presented in educational materials.

The agency disagrees with the comments that stated that the proposed statements regarding sources of folate were overly focused on food. Such comments imply that FDA was biasing the statements against dietary supplements. In fact, each example included dietary supplements in the list of sources of folate (e.g., fruits, vegetables, enriched grain products, fortified cereals, and dietary supplements). The agency also disagrees that the educational effectiveness of the claim is reduced by inclusion of the proposed statement because statements of this type provide, in an abbreviated form, information on sources of folate about which a consumer may be unaware.

In the context of a total diet, the consumer needs flexibility in deciding how to increase folate intake. Provision of this information is consistent with section 403(r)(3)(B)(iii) of the act, which states that the claim shall be stated in a way that enables the public to understand the relative significance of the claim in the context of the total daily diet. Awareness of the food sources of folate, including dietary supplements, will assist women in recognizing the significance of the claim in the context of the total diet. Provision of information on sources of folate in the health claim will assist consumers by making them aware that specific foods and dietary supplements contain folate.

However, FDA recognizes that while there has been a noticeable increase in the use of health claims over the last 2 years, the number of products that bear health claims is not as great as the agency had anticipated. The agency is therefore interested in simplifying claims to facilitate their increased use. The agency is particularly interested in removing so-called "required" elements that are not necessary to ensure that the claims are truthful, not misleading, and scientifically valid. While the agency agrees with the comments that supported inclusion of information on the dietary sources of folate, and while it supports health claim statements that include examples of dietary sources of this nutrient, the agency is concerned that requiring such specific information will increase the length of the claim and may dissuade manufacturers from including it in their labeling.

In comment 14 of this document, the agency concluded that information regarding overall improvement in a woman's diet and nutrition throughout her childbearing years is of considerable importance because pregnancy outcome

depends upon adequate intake of a wide range of nutrients. The agency is adopting § 101.79(c)(2)(i)(H), which requires that the health claim state that there is a need for a healthful diet as well as adequate folate intake. FDA has concluded that this information is necessary to ensure that the claims have proper balance.

The agency is persuaded that shorter claims that state the need for a healthful diet, without reference to specific foods, will meet the objective of encouraging broader use of the claim while alerting women to the importance of overall diet during the childbearing years. Therefore, FDA is requiring that claims state that adequate folate needs to be consumed as part of a healthful diet (see section II.C.5. of this document, and new § 101.79(c)(2)(i)(H)) without identifying specific sources. The appearance of the claim on a wide range of qualifying foods will itself convey information about the variety of sources of folate available to women as part of a healthful total diet.

Therefore, the agency is removing proposed § 101.79(c)(2)(ii)(B) in its entirety and is adding in the codified language a provision (§ 101.79(c)(3)(vii)) for optionally including in the claim information that identifies sources of folate. Because of these changes, FDA has adopted proposed § 101.79(c)(2)(ii)(C) as § 101.79(c)(2)(ii)(B).

#### 4. Identifying the Health-Related Condition

In developing proposed § 101.79(c)(2)(i)(C), FDA considered whether women might be confused or not understand the term "neural tube defect" and provided for some qualification of this term through use of alternate phrases such as "the birth defect spina bifida," "the birth defects spina bifida and anencephaly," "spina bifida and anencephaly, birth defects of the brain or spinal cord," and "birth defects of the brain or spinal cord, spina bifida and anencephaly."

22. The agency received several comments regarding these proposed synonyms. A comment agreed with the agency that the health-related condition must be specified and stated that the agency's proposed synonyms were appropriate. Another comment noted that "anencephaly" is not a familiar term, and that a phrase such as "certain serious birth defects, neural tube defects" is preferable. Another comment recommended that only the statement "neural tube defect" be allowed because it is the more appropriate and accurate term, and because consumers will benefit from seeing the same identifying

statements in health claims on many products. Several comments, however, asserted that consumers will not understand "neural tube defects" and stated that a more understandable term might be "birth defects of the brain and/or spinal cord."

The agency has considered these comments and concludes that the term and qualifiers provided in its proposed rule, i.e., "neural tube defects," "the birth defect spina bifida," "birth defects spina bifida and anencephaly," "spina bifida and anencephaly, birth defects of the brain or spinal cord," and "birth defects of the brain or spinal cord anencephaly or spina bifida," will allow manufacturers considerable flexibility in crafting claims and in educating consumers. The agency is also persuaded to include the option of using the simpler terms "birth defects of the brain or spinal cord" or "brain or spinal cord birth defects" and has modified § 101.79(c)(2)(i)(C) accordingly. The agency accepts the suggestion that use of the latter terms will make the claims simpler and more useful to consumers because the phrase may be more understandable than phrases that include medical terms such as "neural tube defects" or "anencephaly."

The agency also considered whether use of the very general terms "some birth defects" or "some serious birth defects" would be appropriate. As discussed in its January 1993 final rule on folate and neural tube defects (58 FR 2606 at 2610), the act requires that claims on foods be truthful and not misleading. The agency recognizes that, based on the results of the Medical Research Council trial, the association between folate intake and birth defects is limited to neural tube defects. The Medical Research Council trial found that folic acid, while significantly reducing the risk of neural tube defects in women at high risk of recurrence of this complication, did not significantly alter the incidences of a wide variety of other birth defects in the population studied (Ref. 14). Similarly, Czeizel et al. (Ref. 15) reported that the results of the Hungarian trial that studied use of a multivitamin/multimineral supplement containing 0.8 mg of folic acid showed no reduction in incidences of birth defects other than neural tube defects.

FDA also points out that the prevalence of neural tube defects in the United States has been steadily declining in recent decades, and that the estimated incidence is presently about 1 in 1,600 births (Ref. 25). Currently, estimated incidences of other serious birth defects are considerably higher than that for neural tube defects. For

instance, estimated incidences are 1 in 115 for birth defects involving the heart and circulation, 1 in 130 for those involving the muscles and skeleton, 1 in 135 for those involving the genital and urinary tract, 1 in 235 for those involving the nervous system and eye, 1 in 735 for club foot, and 1 in 635 for chromosomal syndromes (Ref. 25).

Because neural tube defects constitute a relatively small fraction of all birth defects, women should not be misled into a false sense of security that they can affect their risk of all birth defects through diets adequate in folate. The agency has therefore decided not to include use of the more general terms "some birth defects" or "some serious birth defects" because use of such terms would fail to disclose the material fact that the food substance/disease relationship is specifically between folate and neural tube defects. Use of such general terms can create the impression that adequate folate intake will reduce a woman's risk of other serious birth defects, and women might, as a result, discount risk factors for other birth defects (e.g., alcohol use, drug abuse).

#### 5. Safe Upper Limit of Daily Intake

Sections 403(r)(3)(A)(ii), 402(a), and 409 of the act establish that the use of a substance in a food must be safe. Based on concerns discussed in the Federal Register of January 6, 1993 (58 FR 2606), the agency concluded that it could not authorize a health claim on folate and neural tube defects at that time. The agency was concerned that the possibility exists that folic acid itself could be a substance that increases the risk of a disease or a health-related condition in persons in the general population (see section 403(r)(3)(A)(ii) of the act).

Recognizing the potential for adverse effects from high intakes of folate, PHS included a caution statement in its recommendation that "because the effects of higher intakes are not well known but include complicating the diagnosis of vitamin B<sub>12</sub> deficiency, care should be taken to keep total folate consumption at <1 mg per day, except under the supervision of a physician" (Ref. 5).

In § 101.79(c)(2)(i)(G), FDA proposed to require a statement as part of the health claim on fortified foods in conventional food form and on dietary supplements containing more than 25 percent of the RDI for folate per unit or per serving that 1 mg of folate per day is the safe upper limit of intake. The agency noted that the availability of the health claim would likely encourage increased intakes of health-claim

labeled foods, and that, if intakes of highly fortified foods and dietary supplements were increased, it could result in folate intakes above the level known to be safe.

The agency received comments addressing two issues related to safe use of foods bearing health claims: (1) Is there a need for concern about a safe upper limit of daily intake? (2) If so, should a statement identifying a safe upper limit of intake be included in a health claim, and how should such a statement be worded?

a. *Need for concern about a safe upper limit of daily intake.* FDA tentatively concluded that, under certain circumstances, there was a need to disclose the safe upper limit of intake in the health claim and tentatively decided to use 1 mg per day (1,000 mcg; 250 percent of the DV) of total folate as the upper limit for such intake (58 FR 53254 at 53273).

The agency noted in the final rule of January 6, 1993 (58 FR 2606 at 2612), and the proposed rule of October 14, 1993 (58 FR 53254 at 53266), that there is a general paucity of evidence on the safety of daily folate intakes above 1,000 mcg (1 mg). The agency noted that there may be risks attendant upon increased consumption of folate for some groups in the population. The agency stated that, at the present time, the potential adverse effect that has been most extensively documented is a masking of anemia in persons with vitamin B<sub>12</sub> deficiency, while irreversible neurologic damage progresses. Other groups at risk from excessive intakes of folate include pregnant women, persons on antiepileptic (i.e., antiepileptic) medications, and those on antifolate medications. There were no data to identify the magnitude of other possible risks of increased folate intake or to establish safe use at daily intakes above 1,000 mcg.

In its proposal of October 14, 1993 (58 FR 53254 at 53266), the agency described how it had reached its tentative decision that 1 mg of total folate per day was the safe upper limit of intake. Based on its review of the scientific literature and its discussions with the Folic Acid Subcommittee, the agency tentatively concluded that: (1) For those with vitamin B<sub>12</sub> deficiency, there was little likelihood of problems at daily intakes lower than 1 mg (58 FR 53254 at 53268 to 53270); (2) an upper limit of intake of 1 mg of folate per day was safe for pregnant women and for persons with epilepsy; (3) doses of folic acid of up to 1 mg per day have not been reported to reduce the effectiveness of medications that interfere with folate metabolism; (4) effects of long-term continuous exposures of body tissues to

elevated blood levels of folic acid, which occur when the body's capacity to metabolize folic acid is exceeded, have not been evaluated; and (5) there have been no long-term studies to quantitate the effects, if any, of increased folate intake on the metabolism of other nutrients.

The agency stated (58 FR 53254 at 53268) that it knew of no data that would support the long-term safety of continuous daily folate intakes of more than 1 mg. The agency, noting that the value of 1 mg for a safe upper limit of daily folate intake could be modified if data were available to support such a decision, solicited comments and data on this point.

In addition, the agency described how it had reached its tentative decision that a statement that 1 mg of total folate per day was the safe upper limit of daily intake should be required on products bearing the health claim and fortified above 25 percent of the RDI for folate. The agency's tentative conclusion was based on, among other considerations: (1) The scientific evidence, and the view expressed by experts, that there are no data to ensure that adverse effects are not likely to occur at daily intakes above 1 mg (Refs. 6, 7, 8, and 26); (2) the PHS recommendation that folate intake of women of childbearing age should not exceed 1 mg per day (Ref. 5); and (3) the support by the Folic Acid Subcommittee of FDA's use of 1 mg of total folate per day as a safe upper limit guide when considering fortification strategies. The upper safe limit of intake that FDA proposed was based on its best scientific judgment at the time. The agency solicited comments and data on its tentative judgment.

Some comments expressed uncertainty regarding an amount that would represent a safe upper limit of daily intake of folate, while other comments strongly agreed or strongly disagreed with FDA's proposal that 1,000 mcg of total folate per day is the safe upper limit of intake.

The agency did not receive any data relating to safety of long-term intakes of folate at levels above 1 mg per day for any of the groups considered at potential risk from increased intakes.

23. Several comments noted that the agency should not misconstrue the absence of safety data on folate intakes of 1 to 4 mg (1,000 to 4,000 mcg) per day as evidence of the absence of harm; that because daily intakes for the general population are well below 1 mg, it has never been established that 1 mg per day of folate from all sources is a safe daily upper limit; and that the upper safe limit of intake for African-Americans, and perhaps Hispanic

Americans, is not known. Several comments noted that pernicious anemia has an earlier age-at-onset among African-Americans than among Caucasians, and that vitamin B<sub>12</sub> deficiency is not rare in persons with sickle cell anemia. Another comment noted that the level of folate that will accelerate the neurologic disorders of vitamin B<sub>12</sub> deficiency is unknown, and that physicians see patients who have been taking folic acid supplements who present with neuropsychiatric disturbances. Another comment noted that there were uncertainties regarding effects of chronic exposures of children, whose requirements for folate are lower than those of adults, to increased intakes of folic acid. Uncertainties regarding safety of increased intakes of this nutrient were the major factor in the opposition in the Folic Acid Subcommittee/Food Advisory Committee to FDA's proposed rules (Ref. 8).

Many comments agreed with FDA's estimate of 1 mg of folate as an upper safe limit of intake given the paucity of information concerning the possible risks of excess folate intakes. Other comments noted that the masking of pernicious anemia is real, but that there is no evidence for folate toxicity at daily intakes of 1 mg/day or less. The comments said that the value of 1 mg/day has, therefore, emerged as being safe. Other comments recognized that overconsumption of folate may complicate the diagnosis of vitamin B<sub>12</sub> deficiency, but that there is limited evidence regarding effects of intakes of folic acid between 400 mcg and 5,000 mcg per day.

FDA notes that a major factor in both the Folic Acid Subcommittee's and the Food Advisory Committee's concern about FDA's proposals was the fundamental issue of lack of documentation of safety of long-term daily intakes at levels above 1,000 mcg (Ref. 8). The agency is also aware that the Committee members expressed considerable concern about the lack of information on the size of the population potentially at risk from increased intakes of folate. Specifically, the agency did not receive data regarding potential adverse effects of increased folate intakes in African-American women or in children. The agency notes that the absence of data on long-term effects of increased folate intakes does not allow the agency to adequately identify those potentially at risk.

As stated above, the agency is not aware of any data that establish the safety of long-term intakes of folate above 1,000 mcg per day. The absence

of any data that allow systematic evaluation of intakes above this level means that potential risks and at-risk groups cannot be adequately defined or described. FDA notes that some members of the Folic Acid Subcommittee and most folate and vitamin B<sub>12</sub> experts submitting comments (Ref. 8) were concerned about the lack of documentation of safety of daily long-term intakes of folate above the level of 1 mg/day. In addition to concerns regarding those with low vitamin B<sub>12</sub> status, other safety concerns included uncertainties of effects of increased folate intakes by young children and the unknown physiological significance of circulating free folic acid in the blood, particularly in pregnant women. In its proposed rule (58 FR 53254 at 53269), the agency summarized evidence from the scientific literature that high levels of free folic acid are not normally found in the circulation, and that folic acid is concentrated in crossing the placenta and accumulates in fetal tissues. The agency also noted that no information is available to ascertain whether developing neural tissue is protected from the neurotoxic effects of very high circulating levels of free folic acid. None of these issues were addressed in comments that the agency received.

Comments that disagreed with FDA's proposal to consider 1,000 mcg folate/day as the safe upper limit of intake raised several issues which are considered below:

i. *Basis for a safe upper limit: Synthetic folic acid versus total folate.*

24. A comment stated that the limit should be based on supplemental synthetic folic acid only because only this form has been associated with masking of the anemia of pernicious anemia. This issue of whether the upper limit should be based on total folate or on synthetic crystalline folic acid was raised in several comments, with some comments of the opinion that it was appropriate to use estimated consumption of folate from all sources in defining the safe upper limit of intake and others recommending use of "crystalline folic acid" only.

The agency disagrees that the safe upper limit of daily intake should be based on "crystalline folic acid" rather than total folate from all sources. FDA notes that the distinction between "synthetic folic acid," referring only to crystalline folic acid, and "folate," referring only to naturally occurring food folates, with respect to the 1,000 mg/day estimate of safe daily intake, is an artificial one and is not consistent with what is known about the nutritional interrelatedness of a variety

of folate vitamin forms in providing coenzyme forms of the vitamin for meeting the body's needs for this essential nutrient. Issues relating to "folic acid" versus "folate" are discussed in response to comment 6 of this document.

Metabolic needs for folate are met from body pools of reduced coenzymes, regardless of whether these coenzymes are derived from synthetic folic acid or from naturally occurring food folates. While it is true that evidence relative to the masking of the anemia of vitamin B<sub>12</sub> deficiency has been obtained from persons who consumed or were treated with synthetic folic acid, such individuals were also consuming unknown quantities of folate from foods. Thus, total daily folate exposures associated with the masking have not been quantified, and the effect of food folates on adverse effects is not known. It is also not known whether the variable responses, in terms of masking effects, to low levels of folic acid in supplements are the result of differences in folate intakes from background diets or of other factors that are currently not understood. For these reasons, it is not possible to attribute all adverse effects solely to crystalline folic acid.

In addition, high intakes of food folates can have adverse effects in persons with poor vitamin B<sub>12</sub> status. With respect to nonpernicious anemia-related vitamin B<sub>12</sub> deficiency, Sanders and Reddy (Ref. 27) noted that megaloblastic anemia is rarely encountered in Caucasian vegetarians and vegans because of their high intakes of folate. These authors reported that, for example, the folate content of diets of vegan children aged 6 to 13 years was twice as high as that of omnivorous children aged 7 to 12 years (Ref. 27). Because the high folate intakes would at least temporarily improve the associated anemia, vitamin B<sub>12</sub> deficiency usually presents with neurological signs and symptoms in infants (Ref. 27). Herbert reported that studies over several decades have all indicated that major myelin synthesis damage from vitamin B<sub>12</sub> deficiency with only minor hematopoietic (i.e., hematologic) damage reflects better folate status because folate improves hematologic, but not neurologic, manifestations of the deficiency (Ref. 28). He also found generally higher red cell folate in persons with greater myelin damage (that only vitamin B<sub>12</sub> deficiency produces) than in persons with greater hematologic damage (which deficiency of either folate or vitamin B<sub>12</sub> produces) (Ref. 28).

The observations above suggest that a safe upper limit of daily intake is more

accurately based on total folate intake than on just intake of crystalline folic acid because under conditions in which vitamin B<sub>12</sub> utilization or intake is limited (i.e., in pernicious anemia or in nonpernicious anemia-related vitamin B<sub>12</sub> deficiency), either crystalline folic acid or food folate may cause adverse effects when consumed in excess.

The agency noted in response to comment 6 of this document, that use of a distinction between "folic acid" and "folate" is inconsistent with the PHS recommendation, which uses these terms interchangeably (Ref. 5), and with advice provided by FDA's and CDC's advisory panels. Moreover, use of such a distinction is not supported by recent statements from experts on folate and vitamin B<sub>12</sub> (Refs. 7, 8, and 26). Therefore, the agency concludes that the safe upper limit of daily intake should be based on total folate intake (i.e., on consumption of folate from all sources).

ii. *Lack of evidence of untoward effects of increased intakes.*

25. Several comments that disagreed with the agency's tentative conclusion that 1 mg folate per day from all sources is the safe upper limit of intake stated that there is no evidence that maximum intakes of 1,500 mcg to 2,000 mcg will result in any untoward effects. Another comment reviewed the literature describing the effects of intakes of 1,000 to 5,000 mcg folic acid per day in persons with vitamin B<sub>12</sub> deficiency and concluded that the literature did not reveal any substantial safety concerns. Another comment stated that 5,000 mcg/day should replace 1,000 mcg/day as the upper limit of safe intake.

The agency is aware that the literature describing the effects of intakes of folic acid between 1,000 and 5,000 mcg per day is very limited but disagrees that there is no evidence of untoward effects of daily folate intakes of 1,500 to 2,000 mcg per day, and that 5,000 mcg per day should be identified as the safe upper limit of intake.

The literature describing the effects of daily intakes of 1,000 to 5,000 mcg folic acid includes three uncontrolled intervention trials involving 15 persons (Refs. 29, 30, and 31) and 16 case reports (Refs. 32, 33, 34, 35, 36, and 37). These reports represent a very small data base, with information from a total of only 31 individuals. Moreover, the agency notes that, among these data, exposures of 9 individuals to daily intakes of 1,000 to 5,000 mcg folic acid lasted for less than 30 days (e.g., Refs. 30, 31, 32, and 33). Therefore, these reports are not useful in assessing the safety of life-long exposures. However, hematological responses that could lead to a delay in the diagnosis of vitamin

B<sub>12</sub> deficiency were observed in 9 of the 16 patients (i.e., in more than 50 percent) whose daily oral intakes of folic acid were in the range of 1,000 to 5,000 mcg and continued for 1 month or more (Refs. 29, 32, 33, 35, and 37). Thus, the limited scientific literature shows that approximately half of the patients with pernicious anemia associated with vitamin B<sub>12</sub> deficiency will respond to folate at doses between 1,000 and 5,000 mcg per day when they are given the vitamin for relatively short periods of time (e.g., several months).

In addition, in discussing safety issues in its proposed rule (58 FR 53254 at 53267), the agency noted that, although there was a lack of systematic evaluation of the effect of folic acid on the anemia of vitamin B<sub>12</sub> deficiency at intakes of less than 5,000 mcg per day, several case reports have described hematologic improvement in pernicious anemia patients with doses of folic acid lower than 1,000 mcg/day (e.g., at 200 to 500 mcg/day; Refs. 38, 39, 40, 41, 42, 64 through 65, and 72 through 74). Thus, adverse effects have been reported at daily doses of less than 1,000 mcg, at doses of 1,000 to 5,000 mcg, and at doses greater than 5,000 mcg.

iii. *Lack of evidence of toxic effects of increased folate intakes in pregnant women.*

26. Another comment that disagreed with the agency's tentative conclusion noted that millions of pregnant women have taken prenatal vitamins containing 1,000 mcg folic acid, that folic acid at dosages of 4,000 mcg per day has been extensively studied in pregnant women, and that no toxic effects have been shown in healthy individuals.

The agency disagrees with the comment that folic acid at doses of 4,000 mcg per day have been extensively studied in pregnant women and are without toxic effects. The agency recognizes that pregnant women take prenatal supplements which usually contain 800 mcg of folic acid, and that such supplements have been in use for many years. FDA notes that, while there is no evidence that 800 mcg of folic acid per day (i.e., the RDA level for pregnant or lactating women) is unsafe for this group, such dosages are usually taken only during the second and third trimesters of pregnancy or during lactation to meet specific nutritional needs for limited periods of time and are usually taken under physician supervision. The Institute of Medicine in *Nutrition During Pregnancy* stated that the safety of large doses of folic acid in pregnant women has not been systematically determined (Ref. 43).

The agency notes also that the comment that folic acid at doses of 4,000 mcg per day has been extensively studied in pregnant women, and that such doses are without toxic effects, is not substantiated by the scientific data. In the only study utilizing 4,000 mcg folic acid/day, the Medical Research Council (MRC) trial, about 910 women took supplements containing 4,000 mcg of folic acid from the time of randomization into the trial until the 12th week of pregnancy (Ref. 14). At the conclusion of the study, the author stated that, although the MRC trial had sufficient statistical power to demonstrate the efficacy of the intervention, it did not have sufficient power to answer the question of safety for public health purposes. Consequently, this study does not provide a basis on which to determine whether the use of 4,000 mcg/day of folic acid by pregnant women is safe.

Thus, the agency has not received any data or information that would persuade it that any level other than 1 mg (1,000 mcg) folate per day is the appropriate safe upper limit of intake for pregnant women.

iv. *Adverse effects in those with vitamin B<sub>12</sub> deficiency can be detected with clinical care.*

27. Another comment disagreed with the proposed 1,000 mcg safe intake limit and noted that adverse effects of high intakes of folate with respect to vitamin B<sub>12</sub> deficiency can be detected with clinical care. Other comments stated that the issue of masking of vitamin B<sub>12</sub> deficiency was overstated and predated modern clinical nutrition.

FDA is aware that, in many instances, the adverse effects of increased folate intake associated with the masking of the anemia of vitamin B<sub>12</sub> deficiency can be detected with clinical care but disagrees that this fact provides adequate justification for increasing the safe limit of daily intake. The agency notes that measurements of vitamin B<sub>12</sub> status are not performed on a routine basis by physicians. Currently, there are no population-based data on how many people in the United States have undiagnosed vitamin B<sub>12</sub> deficiency and thus might be at risk from increased intakes of folate. The agency noted in the January 6, 1993 final rule (58 FR 2606 at 2615), that significant percentages of the elderly, demented patients, acquired immune deficiency syndrome (AIDS) patients, and patients with malignant diseases have subnormal vitamin B<sub>12</sub> levels without having any of the classical manifestations of vitamin B<sub>12</sub> deficiency. Lindenbaum et al. recently reported that the prevalence of vitamin B<sub>12</sub> deficiency was greater than

12 percent in a large study (n=548) of free-living elderly Americans (Ref. 44). In addition, 5 to 10 percent of all patients, regardless of age or clinical status, are found to have low serum vitamin B<sub>12</sub> levels (58 FR 2606 at 2615). Little is known about whether folate supplementation would have any adverse effect on such persons, who are far more numerous in the U.S. population than are persons with pernicious anemia.

The argument that adverse effects in persons with vitamin B<sub>12</sub>-related problems can be identified with clinical care fails to consider whether such persons, who may be unaware of their vitamin B<sub>12</sub> status, would recognize an adverse effect as being the result of increased folate intake, and whether they would seek medical attention if subtle adverse effects were experienced. Thus, the agency concludes that the argument that adverse effects in persons with vitamin B<sub>12</sub>-related problems can be identified with clinical care does not provide a sufficient basis for increasing the safe upper limit of intake for such persons or for other persons in the general population for whom there are currently no data to establish the effects, if any, of high intakes of folate. In developing its proposed rule,

FDA was aware of the contentious nature of a proposed upper limit and specifically asked for data on this issue. This topic was also extensively discussed by FDA's Folic Acid Advisory Committee and Food Advisory Committee (Refs. 7 and 8). No data were submitted in any of the comments that addressed the issue of the safety of intakes above 1,000 mcg per day either for persons in the general population or for any of the groups identified as potentially at risk from increased folate intakes. The agency also notes that its position regarding use of 1,000 mcg folate per day as the safe upper limit of daily intake was supported by all comments from individuals with known expertise in folate and vitamin B<sub>12</sub> metabolism and related diseases.

Because there are inadequate data and information on the safety of consuming more than 1,000 mcg folate per day, the agency is unable to conclude that there is a reasonable certainty of no harm to persons consuming more than 1,000 mcg folate per day. In the absence of data on high intakes of folate, the agency is unable to adequately define the nature or magnitude of potential risk from increased folate intakes. At this time, the agency has no data to support a conclusion of safe use of folate above 1,000 mcg per day or data that would provide a basis for a change from the proposed upper limit of 1,000 mcg per

day to an upper limit of 5,000 mcg per day. In addition, for the reasons explained above, the agency has not been persuaded by the comments that it should consider synthetic folic acid as the only active form of the vitamin and thus base its estimate of a safe upper limit of intake on this form of the vitamin only.

The agency therefore concludes that, because of the lack of evidence of safe use at intakes greater than 1,000 mcg folate daily, and the potential for serious harm to some persons from such intakes, daily intakes above 1,000 mcg by the general population should not be encouraged.

b. *Including a safe upper limit of daily intake in the claim.* In recognition of comments and safety concerns discussed in its proposal, FDA, in § 101.79(c)(2)(i)(G), proposed to require a statement on fortified foods in conventional food form and on dietary supplements that contain more than 25 percent of the RDI (i.e., more than 100 mcg per reference amount customarily consumed or, for supplements, per unit) about the maximum safe daily limit for folate consumption. The agency proposed that such a statement (e.g., "Folate consumption should be limited to 1,000 mcg per day from all sources.") was necessary to prevent the health claim from being misleading regarding potential risks from excessive intakes.

In the October 14, 1993 proposal (58 FR 53254 at 53282), the agency, noting that the safe upper limit of intake was 1 mg (1,000 mcg), stated that a fortified food that contains more than 100 mcg folate per serving contributes more than 25 percent of the RDI and more than 10 percent of the daily limit. Therefore, it continued, consumption of such foods should be monitored by the consumer, so that he or she will not consistently or significantly exceed the upper limit.

In its proposed rule (58 FR 53254 at 53282), the agency also noted that it was not proposing to require that this statement be included in claims on the relatively small number of conventional foods that contain more than 100 mcg of folate without fortification (e.g., dark green leafy vegetables, certain legumes). The agency stated that it believed that there is no need for the consumer to monitor intakes of these foods because their folate content consists of reduced pteroylpolyglutamates whose bioavailability is generally considered lower than that of the folic acid (i.e., pteroylmonoglutamate) added as a fortificant to foods. The agency received many comments on this aspect of the proposal.

c. *General comments.*

28. Comments supporting inclusion of a caution statement in health claims stated that an admonition regarding excessively high intakes is absolutely essential in the health claim, and that the agency must require a meaningful and useful disclosure regarding the risks of excess intake. One comment stated more specifically that health claims related to folate and neural tube defects should be balanced by a warning statement that increased intakes of folate may increase the frequency of irreversible neurologic damage from vitamin B<sub>12</sub> deficiency. A related comment stated that, among Black and Hispanic females, folic acid fortification or supplementation is likely to do more harm than good, and that a caution statement was important for such groups. One comment recognized the need to set upper limits of safe intake but noted that, in the absence of strong evidence, it is inappropriate to warn consumers about potential adverse effects and detract from the benefits of the health claim.

Other comments supported the use of a statement of a safe upper limit of intake but found FDA's proposed language in § 101.79(c)(2)(i)(G) and in the model health claims (§ 101.79(d)) unsatisfactory because the agency failed to provide specific information on the potential adverse effects of overconsumption and failed to identify the subpopulations at risk from high intakes (e.g., the elderly).

The agency does not agree that it is inappropriate to warn consumers about the potential adverse effects of increased folate intake because adverse effects have been documented in the scientific literature. The agency's responses to comments 23, 25, and 27 of this document make clear that, for some population groups, there are risks attendant upon increased folate intake. Such groups include those with vitamin B<sub>12</sub> deficiency and African-American women. As noted above, the agency did not receive data providing evidence rebutting the risks of folate intakes above 1 mg per day (1,000 mcg/day) for these and other at-risk groups, such as pregnant women, children, persons on antiseizure medications, or persons on antifolate medications.

Therefore, the agency agrees with the comments that stated that it should require that a useful statement regarding risks of excessive intakes be included in the health claim. In response to the comment that the model health claims were unsatisfactory because they failed to identify specific subpopulations at risk from increased intakes (e.g., the elderly), the agency is advising that it will not require identification of specific

at-risk groups in the caution statement because the limited data available from populations consuming folate at the level of 1 mg per day (1,000 mcg per day) and above do not allow an adequate identification of all such groups to be made. Identification in the claim of only some of the groups at risk (e.g., the elderly) would be misleading because persons in other at-risk groups that were not identified in the claim could conclude that because they were not mentioned, they were not at risk from high intakes.

*d. Inappropriate to include caution statement only on fortified foods and supplements.*

29. Other comments stated that it was inappropriate to single out only fortified foods or supplements that contain folate above 25 percent of the DV for carrying a warning statement.

The agency proposed not to require the caution statement in health claims on the relatively small number of conventional foods that contain more than 100 mcg of folate without fortification (e.g., dark green leafy vegetables, certain legumes) because many of these foods are not consumed on a daily basis, and even when consumed regularly, the bulk and energy value of such foods tends to limit their consumption.

The agency has reevaluated whether foods that are naturally high in folate (e.g., those containing more than 25 percent of the DV) should carry the caution statement proposed for fortified foods or supplements containing more than 25 percent of the DV. The agency agrees with the comment that it is inappropriate to single out fortified foods and supplements for a caution statement because there is no justification for distinguishing between added and naturally-occurring nutrients. This decision is consistent with the agency's conclusion (see comment 23 of this document) that total folate intake from all sources needs to be considered in arriving at a safe upper limit of daily intake. For this reason, FDA has decided to require that the modified caution statement described in comment 31 of this document appear on any conventional food or dietary supplement that meets the criteria set out in § 101.79(c)(2)(i)(F).

*e. Optional caution statement.*

30. Another comment advised the agency to permit the identification of the 1,000 mcg per day limit as optional information.

The agency rejects this comment. Given the point of the health claim message, it is unlikely that an optional caution statement would be included in most health claims. Therefore, most

consumers would not be alerted to the potential adverse effects of high levels of folate or might assume that claim-bearing products without the caution statement were safer than products that bore a claim that included the caution statement. Consumption of products bearing the caution statement might come to be associated with potential adverse effects, while consumption of other products with an identical folate content that did not bear the caution statement would not be associated with such potential adverse effects. Because potential adverse effects are related to increased intakes of folate from any source, it would be illogical for the agency not to require the caution statement on all products that carry the health claim and that meet the criteria for the caution statement. Claims on products that meet the criteria and that fail to carry the caution statement would be misleading because they would fail to alert consumers to the material fact that there may be risks attendant upon excessive folate intakes.

*f. Upper limit of safe intake expressed as percent DV.*

31. Another comment agreed with the use of a caution statement but felt that the safe upper limit of intake should be expressed as percent of the DV.

The agency agrees with this comment because this method of communicating the safe upper limit of intake will provide consistency with the nutrition label, thereby enhancing the comprehensibility of the information. The agency notes that, as stated in response to comment 19 of this document and in the codified language in § 101.79(c)(2)(i)(F), the upper limit of daily intake is to be expressed in the claim as percent of the DV, with manufacturers having the option of including the microgram equivalent in parentheses (e.g., 250 percent DV (1,000 mcg)).

*g. Limit caution statement to products with 100 percent DV.*

32. Several comments said that a warning statement should be limited to higher-dose foods or dietary supplements (those containing 100 percent or more of the DV) unless further research and monitoring demonstrate that the risks of increased folate intakes from lower-dose foods or supplements are also significant. Other comments argued that there is no need to include a warning statement and noted that supplements and cereals with 100 percent of the DV have never carried such a warning statement. Other comments expressed the opinion that the warning statement would discourage increased consumption of folic acid supplements.

The agency has considered whether requiring that the caution statement appear in claims on foods or dietary supplements that contain more than 25 percent of the DV is too restrictive. The agency recognizes that such a requirement would require that caution statements appear as part of health claims on a wide range of products that contain more than 100 mcg folate per serving (e.g., dietary supplements, breakfast cereals) that have not previously carried such a statement. The agency agrees with the comment that the result of such caution statements could well be to discourage consumption of such products. It was not the agency's intent to cause such a result because breakfast cereals and dietary supplements have traditionally been important sources of folate for consumers who use them. Additionally, in the case of many dietary supplements, a statement regarding daily consumption (e.g., "consume one per day") is already included in the labeling and serves to inform consumers as to the appropriate daily intake.

The agency notes, however, that the health claim is intended to encourage women to increase their intakes of folate, and that the claim is likely to encourage some women to consume more of particular products, particularly those bearing the claim that are very high in folate, than they might otherwise consume. Thus, a caution statement regarding excessive intakes is appropriate on foods that contain very high levels of folate because the possibility is created by the claim itself that some women will achieve high folate intakes.

The agency has concluded that a statement about high consumption of folate is necessary if a product contains more than 100 percent of the DV (i.e., 400 mcg when labeled for use by adults and children 4 or more years of age; 800 mcg when labeled for use by pregnant or lactating women; 58 FR 2206 at 2213, January 6, 1993; Food Labeling; Reference Daily Intakes and Daily Reference Values). Such an amount of folate would exceed not only the DV's but the PHS recommended folate intake for women of childbearing age. Thus, the caution statement is required only on products that contain more than current recommended daily intakes of folate per serving.

The agency has redesignated proposed § 101.79(c)(2)(i)(G) as § 101.79(c)(2)(i)(F) and has modified this provision to read that:

Claims on foods that contain more than 100 percent of the Daily Value (DV) (400 mcg) when labeled for use by adults and children 4 or more years of age, or 800 mcg



when labeled for use by pregnant or lactating women) shall identify the safe upper limit of daily intake with respect to the DV. The safe upper limit of daily intake value of 1,000 mcg (1 mg) may be included in parentheses.

*h. Upper limit useless without reference to intake goal.*

33. Other comments opposed including a reference to the upper limit of 1,000 mcg per day in any health claim because, they argued, consumers cannot determine their total daily intakes from all sources. These comments noted that stating an upper limit was useless unless all food types were labeled with their folate content. Another comment opposing the inclusion of a warning statement on foods or supplements containing more than 25 percent of the DV stated that inclusion of an upper limit was problematic if reference was not made to the 400 mcg/day intake goal.

The agency recognizes that there was an inconsistency in the way that proposed § 101.79(c)(2)(i)(G) was worded in that the safe upper limit of daily intake was expressed as 1,000 mcg rather than as a percent of the DV. The agency has corrected this inconsistency, as noted above in response to comment 32 of this document.

The agency disagrees that inclusion of the 400 mcg intake goal is necessary to make a caution statement understandable, and that a caution statement is useless unless all foods are labeled with their folate contents. The agency notes that diets that do not contain highly fortified foods and dietary supplements rarely provide daily folate intakes of more than 1,000 mcg. The likelihood of achieving daily intakes exceeding 1,000 mcg arises from consumption of highly fortified foods and dietary supplements, particularly those that contain more than the DV per unit or per serving. Under current labeling requirements, such foods and supplements must, or soon will have to, carry nutrition labeling. The safe upper limit of daily intake will thus appear on those products whose use provides the greatest potential for contributing to overconsumption (e.g., highly fortified foods and supplements whose label bears a health claim that explains a potential benefit of increased consumption). The agency concludes that it is necessary to require inclusion of the caution statement, with the safe upper limit of daily intake expressed as percent of the DV (percent DV), as part of the health claim on such products.

The agency also notes that the availability of the health claim may result in increased consumption of foods with high folate content that carry the claim. The expression of the folate

content as a percent of the DV will help consumers who select a health claim-labeled food that contains more than 100 percent of the DV and that is labeled with a statement that folate intakes should be limited to 250 percent of the DV, to recognize that the product provides more than the full amount of the DV while still leaving a considerable allowance for consumption of other foods of lower folate content. The percent DV labeling will also allow a consumer who selects four health claim-labeled foods that each contain more than 100 percent of the DV to quickly compute that these four products alone will provide more than 400 percent of the DV, an amount in excess of the safe upper limit of daily intake of 250 percent of the DV. Thus, the agency does not believe that explicit reference to the 400 mcg target intake goal is necessary to make the caution statement understandable. The agency advises, however, that manufacturers wishing to include reference to the 400 mcg intake goal may do so (§ 101.79(c)(3)(iv)).

*i. Caution statement on all products with >25 percent DV.*

34. One comment interpreted the proposed regulation to mean that the agency was proposing to require use of a caution statement on all products with more than 100 mcg folate/serving, whether or not they bore the health claim.

This comment misunderstood the proposal. The agency advises that it is requiring that the caution statement be used only on conventional foods or dietary supplements that bear the folate/neural tube defects health claim and that contain more than 100 percent of the DV (400 mcg when labeled for use by the general population or 800 mcg when labeled for use by pregnant or lactating women).

*j. Warnings on supplements without adequate vitamin B<sub>12</sub>.*

35. One comment suggested that the agency should require warnings on supplements that do not provide amounts of vitamin B<sub>12</sub> adequate to provide protection from the potential problem in nearly all cases.

This comment was based on the assumption that the greatest potential for adverse effects of high folate intake is the masking of the anemia of vitamin B<sub>12</sub> deficiency, with continued progression of neurologic damage, and that provision of oral vitamin B<sub>12</sub> will negate this concern. The comment did not provide data or information identifying the amount of oral vitamin B<sub>12</sub> that would protect nearly all persons from masking of a vitamin B<sub>12</sub> deficiency and, thus, the level below

which a warning statement would be required.

The agency disagrees with this suggestion. The agency is aware that very high doses of vitamin B<sub>12</sub> (e.g., about 1 mg; 500 times the RDI for this vitamin) without intrinsic factor (i.e., without the protein factor necessary for the absorption of vitamin B<sub>12</sub> and the factor whose lack causes pernicious anemia) have provided adequate treatment for some persons with pernicious anemia (Ref. 45). It has been suggested, based in part on observations that some patients with pernicious anemia can be maintained on oral vitamin B<sub>12</sub>, that high doses of vitamin B<sub>12</sub> be added to foods and dietary supplements fortified with folic acid to reduce the potential for adverse effects in persons with vitamin B<sub>12</sub> deficiency.

Several experts at a CDC meeting on surveillance for adverse effects of increased intakes of folate (Ref. 26) commented on this suggestion. One expert noted that in the presence of other nutrients (e.g., vitamin C, thiamin, iron), vitamin B<sub>12</sub> may be converted into analogs, some of which may have antivitamin B<sub>12</sub> activity.

In the proposal of October 14, 1993 (58 FR 53254 at 53280), the agency discussed the issue of whether high doses of vitamin B<sub>12</sub> should be added to foods or supplements fortified with folic acid to reduce the potential for adverse effects in persons with vitamin B<sub>12</sub> deficiency. The agency requested comments, specifically data, on the appropriateness, potential effectiveness, and safety of such fortification. The agency did not receive data or other information on this issue.

Given this lack of information, FDA finds no basis to require a warning statement on supplements based on their content of vitamin B<sub>12</sub> because there are no data on the effects of various folate/vitamin B<sub>12</sub> combinations on which to base a warning. In addition, relating a caution statement only to the vitamin B<sub>12</sub> content of a product would fail to recognize the potential adverse effects of increased folate intakes on other population groups, including, as discussed above, pregnant women, children, those on antiepileptic medications, and those on antifolate medications, because it would fail to recognize that potential adverse effects of increased intakes are not limited only to those with vitamin B<sub>12</sub>-related problems.

Because data are not available that address for the general population on the issue of simultaneous fortification of foods or dietary supplements with both folate and vitamin B<sub>12</sub>, the agency cannot establish a level of oral vitamin



B<sub>12</sub> that is sufficient to protect most persons with vitamin B<sub>12</sub>-related problems from the adverse effects of increased intakes of folate. In addition, questions regarding the appropriateness, potential effectiveness, and safety of such an approach remain unanswered. Vitamin B<sub>12</sub> deficiency, including pernicious anemia, is a serious condition, which, if untreated, can lead to irreversible neurological damage. Regardless of the widespread availability of oral vitamin B<sub>12</sub> preparations, patients with pernicious anemia, and others at risk of vitamin B<sub>12</sub> deficiency, should be diagnosed, treated, and monitored by a physician (Ref. 45).

#### 6. Multifactorial Nature of Neural Tube Defects

The general requirements for health claims for conventional foods (§ 101.14(d)(2)(iii)) provide that, where factors other than dietary intake of the substance affect the relationship between the substance and the disease or health-related condition, FDA may require that such factors be addressed in the health claim. FDA has decided that health claims on dietary supplements should be subject to the same requirement (see 59 FR 395 at 425).

It is well-recognized that neural tube defects have many causes, some of which are not related to folate status. Genetic and environmental factors contribute to the multifactorial nature of neural tube defects. Environmental factors associated with neural tube defects include, for example, maternal health, maternal family history of neural tube defects, and maternal use of certain antiseizure medications (see 58 FR 53254 at 53258 for references).

FDA discussed the multifactorial nature of neural tube defects in several sections of its proposed rule. In proposed § 101.79(b)(1), FDA discussed the fact that neural tube defects are caused by many factors and also noted that a significant risk factor is a personal or family history of a pregnancy affected by a neural tube defect. In § 101.79(c)(2)(i)(D), FDA proposed to require that claims state that neural tube defects have many causes, and that claims not imply that folate intake is the only recognized risk factor for neural tube defects. The agency included language to this effect in the agency's proposed model claims (§ 101.79(d)).

The agency received several general comments and new data in response to the sections of the proposed codified language addressing the multifactorial nature of neural tube defects.

##### a. General comments.

36. Several comments agreed that the claim should include information on the multifactorial nature of neural tube defects to be consistent with claims for other diet-disease relationships. These comments asserted that the claims would be misleading if such information were not included. Other comments disagreed that the multifactorial nature of neural tube defects should be recognized in the claim because, for example: (1) Folate is the most important risk factor, or (2) there is no educational value in identifying the multifactorial nature of the condition. Another comment stated that only factors that can be controlled, or those on which women could take action, should be included in the claim.

FDA is in the process of reconsidering the need to include in health claims the fact that the disease that is the subject of the claim has many causes. In the January 1993 final rules on health claims, FDA included this fact as a required element of the claim. However, as discussed below, FDA has come to tentatively conclude, at least in part in response to a petition from the National Food Processors Association (Docket No. 94P-0390), that, at least for most claims, a statement about their multifactorial etiology adds length to the claim without conveying information that would directly affect the dietary choices of the consumers.

The agency is particularly concerned that manufacturers will be disinclined to use unnecessarily lengthy health claims on food labels, that additional verbiage may detract from the central consumer message of the claim, and that, as a result, health claims will be infrequently used, and the benefits of communicating information on diet-disease relationships to consumers through such claims will not be realized.

The issue of manufacturers' reluctance to use lengthy health claims is particularly significant in the case of the folate/neural tube defects health claim because this topic has received much less attention than has been given to chronic illnesses such as osteoporosis, heart disease, and cancer. The lower level of public familiarity with this topic was confirmed in a recent survey conducted for the March of Dimes Birth Defects Foundation regarding knowledge and practices of women of childbearing age in the United States with respect to consumption of folic acid from supplements and breakfast cereals (Ref. 53).

During January and February 1995, the Gallup Organization conducted for the March of Dimes a proportionate,

stratified random-digit-dialed telephone survey of a national sample of 2,010 women aged 18 to 45 years. The response rate was 50 percent. Estimates were statistically weighted to reflect the total population of women aged 18 to 45 years in the continental United States. In response to the question "Have you ever heard or read anything about folic acid?", 52 percent of women reported ever hearing of or reading about this nutrient. Of these, 9 percent answered that folic acid helps to prevent birth defects and 6 percent that folic acid helps to reduce the risk for spina bifida; 45 percent were unable to recall what they had heard or read. Fifteen percent of respondents reported having knowledge of the PHS recommendation regarding the use of folic acid; 4 percent reported that the recommendation was for prevention of birth defects and 1 percent, for the prevention of spina bifida (Ref. 52).

Respondents were also asked "From what you know, is there anything a woman can do to reduce her risk of having a baby with birth defects?" A total of 88 percent of respondents reported that a woman can help reduce the risk for having an infant with birth defects. The most common responses about how to reduce risk were avoiding alcohol and drugs (73 percent), and not smoking (63 percent); 1 percent of women reported that folic acid could reduce risk.

This study found that while most women interviewed recognized that there were a number of factors that might affect their risk of having a baby with a birth defect, there was a low level of awareness that consumption of folate from supplements, breakfast cereals, and other foods may specifically help to reduce their risk of a neural tube defect-affected pregnancy.

The results of the March of Dimes survey are consistent with recent findings by FDA. As part of FDA's ongoing review of its regulations governing health claims, the agency conducted six focus groups in May and June 1995 to evaluate consumer understanding of health claim messages. In a report on these focus groups, Levy (Ref. 54) noted that while almost all participants were aware of health effects of fat, calcium, and fruits and vegetables, very few had heard much about folic acid. Participants appreciated information provided in the folate/neural tube defects model claims but considered it insufficient to inform them as adequately as they wished to be informed.

Thus, recently available information suggests that there is a low level of awareness of the potential impact that

increased folate intake may have on the risk of a serious type of birth defect.

The agency has concluded, based in part on the studies mentioned above, that the need to provide a succinct health claim in this topic area is very important. Succinctness in the claim will increase the likelihood that firms will use it and thus will increase its educational value. To facilitate the use of such a claim by manufacturers, it needs to be no longer than necessary to convey the central consumer message.

With respect to the issue of whether explicit identification of the multifactorial nature of neural tube defects is necessary to prevent the folate/neural tube defects health claim from being misleading, the agency notes that use of the term "may reduce" in the claim describes the potential of folate to affect the risk of neural tube defects and serves to reflect the multifactorial nature of this birth defect. In addition, data obtained in the March of Dimes survey described above indicate that many women already recognize that birth defects in general may have many causes. The agency has therefore concluded that explicit reference to "may have many causes" is redundant when included with the phrase "may reduce."

The agency has concluded that it is not necessary to include explicit reference to the multifactorial nature of neural tube defects in the claim.

The agency notes, however, that the fact remains that neural tube defects are multifactorial in nature. This fact is confirmed by new data of which FDA has become aware and that are discussed in the following section. Because of this fact, the claim must not imply that folate intake is the only risk factor for these birth defects.

Therefore, the agency is modifying § 101.79(c)(2)(i)(D) by deleting the requirement that the claim state that neural tube defects have many causes but is retaining the requirement that claims shall not imply that folate intake is the only recognized risk factor for neural tube defects.

The agency is also advising that manufacturers who wish to do so may include, on an optional basis, information in the claim on additional risk factors for neural tube defects. Information that may be included is described in § 101.79(c)(3)(i).

b. *Data received in comments.* 1. The agency received new data from an Irish study that found that plasma levels of vitamin B<sub>12</sub>, as well as folate, were independent risk factors for neural tube defects (Ref. 51). These data were reviewed at the October 14 and 15, 1993, meeting of the Folic Acid

Subcommittee and are summarized here because the agency did not have the data in sufficient time to include them in its October 14, 1993, proposed rule. Kirke et al. (1993) (Ref. 51) compared values for plasma folate, plasma vitamin B<sub>12</sub>, and red blood cell folate in 81 women who had a neural tube defect-affected pregnancy and 247 control women. Values for all three parameters were significantly lower in case mothers than in control mothers. Plasma vitamin B<sub>12</sub> and red cell folate were both significantly positively correlated in case mothers but not in control mothers. Multiple regression analysis showed that plasma vitamin B<sub>12</sub> and plasma folate were independent predictors of red cell folate in case mothers but not in control mothers.

The authors concluded that plasma vitamin B<sub>12</sub> and plasma folate were independent risk factors for neural tube defects and suggested that the enzyme methionine synthetase was involved directly or indirectly in the etiology of neural tube defects. They noted that the correlation between plasma vitamin B<sub>12</sub> and red cell folate, observed in case mothers only, was difficult to explain on a purely nutritional basis and favored the etiology of neural tube defects as being the result of some metabolic abnormality in the mother, and possibly in the embryo, interacting with maternal plasma levels of folate and vitamin B<sub>12</sub> (Ref. 50).

Mooij et al. (Ref. 46) measured levels of seven vitamins in blood of women who had a neural tube defect-affected pregnancy and reported that such measurements were not suitable for identifying women at high risk of another affected pregnancy. The authors hypothesized that the effect of folic acid was attributable, at least in part, to its overriding a metabolic disorder.

2. The agency received additional new data in a comment relating to a possible role of a deficiency of one or more antioxidant enzymes in the development of neural tube defects. The comment discussed the hypothesis that a genetic defect in antioxidant enzyme systems that protect neuronal membranes from excessive lipid peroxidation may play a role in the etiology of neural tube defects. The comment noted that abnormalities of the neural tube have been documented in cultured rat embryos exposed to oxygen radicals generated in vitro by xanthine plus xanthine oxidase. The severity of these abnormalities, which increases in a dose-responsive manner with exposure to xanthine oxidase, can be moderated by substances with known antioxidant activity such as glutathione,

catalase, L-ascorbic acid (vitamin C), or DL-alpha tocopherol (vitamin E).

This comment provided the results of a pilot study that tested the hypotheses in children with neural tube defects and their immediate families. In testing the hypothesis, the investigators assessed a number of red blood cell free radical-scavenging enzymes in eight families with one or more children with the neural tube defect meningomyelocele. Seventeen healthy adults without a history of neural tube defects served as controls. All meningomyelocele-affected children were found to be deficient in red blood cell glutathione peroxidase, with 5 in the range of moderately to severely deficient. At least one parent of seven of the eight affected children was deficient in red blood cell glutathione peroxidase activity, with four of seven in the moderately to severely deficient range. Nine additional children with meningomyelocele or other neural tube defects (specifically, encephalocele and iniencephaly) were also studied. Red blood cell glutathione peroxidase activities were low in all of the nine additional affected children, with values in six of the nine in the moderately to severely deficient range.

The comment also noted that pterin aldehyde, a contaminant that may be present at a level of about 4 percent in commercially available folic acid preparations, may reduce exposure of the developing neural tube to toxic oxygen free radicals through its activity in inhibiting xanthine oxidase. The comment suggested (Comment 68H to docket 93N-100H) that a combination of genetic factors, deficient antioxidant enzyme capacities, exogenous or endogenous teratogens, periconceptional diets with inadequate amounts of free radical scavenging substances, or suboptimal concentrations of pterin aldehyde-like agents may provide further explanations for tissue-specific injury in some pregnancies.

The comment concluded that, while the mechanisms of neural tube defect formation likely fit into a complex ecogenetic model, a deficiency of one or more antioxidant enzymes may increase the risk for the development of neural tube defects. The comment recommended further study to determine whether reduced antioxidant activity predisposes the embryo to the development of neural tube defects.

c. *Data that were published after the close of the comment period.* 1. Mills et al. (1995) (Ref. 47) reported that women with neural tube defect-affected pregnancies had significantly higher levels of homocysteine than did vitamin B<sub>12</sub>-matched controls. Mills et al. (1995)

(Ref. 47) noted that their study showed that an abnormality of homocysteine metabolism, apparently related to methionine synthase, is present in many pregnancies that resulted in neural tube defects.

2. Mechanistic studies in cultured rat embryos have also provided insights into roles for nutrients in addition to folate in the etiology of neural tube defects. Chambers and coworkers identified autoantibodies (i.e., antibodies directed against tissue components of the same organism) to the extracellular basement membrane (i.e., the noncellular layer underlying the epithelium) protein laminin as an agent that caused neural tube defects in whole embryo cultures (see Ref. 48 for additional references). Such antibodies were found initially in the embryotoxic sera of monkeys with poor reproductive histories. Chambers et al. (1995) (Ref. 48) recently reported that methionine overcomes neural tube defects in rat embryos cultured on sera from monkeys immunized against laminin. The authors noted that the association of autoimmune diseases and fetal loss has received closer attention in recent years, but that neither the mechanisms of fetal loss nor treatments have been well defined (Ref. 48). The authors suggested that epidemiologic studies are needed to establish a possible role for autoantibodies in the etiology of neural tube defects and to determine the efficacy of methionine supplementation in overcoming such defects.

3. Data addressing the etiologic heterogeneity of neural tube defects were also derived from observations that infants and fetuses with isolated neural tube defects have different risk factors than those with neural tube defects occurring with other birth defects and from reported differences in recurrence risks for neural tube defects based on the level of the affected infant's defect (Ref. 49; Shaw et al., 1994, for references). Shaw et al. (1994) (Ref. 49), used population-based case ascertainment by the California Birth Defects Monitoring Program in an ethnically diverse population of more than 700,000 live births and fetal deaths to investigate whether heterogeneity existed among various anatomic and pathogenetic subclasses of neural tube defects for a variety of commonly collected child and parental characteristics. Among cases of anencephaly, increased risks were found for Hispanic white women with risk estimates highest for nonisolated cases. This population-based study showed increased risk for Hispanic women specifically among subclassifications of neural tube defects,

and provides some evidence that further classification of neural tube defects may reveal subgroupings of cases with different etiologies.

Shaw et al. (1995) (Ref. 50) used a case-control study design (549 cases and 540 controls) to investigate whether intake of supplemental folic acid or dietary folate reduced the risk of a neural tube defect-affected pregnancy (Ref. 50). The authors found that women with any use of a folic acid-containing vitamin in the 3 months prior to conception had a lower risk of having an NTD-affected pregnancy. Odds ratios were similar for average daily folic acid intakes of <400 mcg, 400 to 900 mcg, and >900 mcg/day, and thus, no dose-response pattern was apparent. Use of 400 to 900 mcg folic acid/day in the 3 months after conception was also associated with reduced risk of a neural tube defect-affected pregnancy. The authors also observed that women who did not begin using a folic acid-containing vitamin until the second trimester of pregnancy also had a reduced risk of neural tube defects and suggested that although the finding may be indicative of errors in reporting vitamin use in general, it also weakens the attribution of a direct preventive effect of folate on neural tube defects in the study population (Ref. 50).

When race/ethnicity were considered, nonHispanic white women who used a folic acid-containing vitamin in the 3 months before conception had a reduced risk of a neural tube defect-affected pregnancy. However, risk of a neural tube defect-affected pregnancy was not reduced in Hispanic women who consumed a folic acid-containing vitamin in the 3 months before conception. The overall results of this study are consistent with other studies showing associations between folate intake and reduced risk of neural tube defects. However, the data also suggest that the folate-associated reduction in risk may be specific to subsets of the population, primarily nonHispanic women (Ref. 50).

These recent studies are of significance for the insights that they provide into understanding the multifactorial etiology of neural tube defects. They support the hypothesis that neural tube defects are not the result of a wide-spread nutritional deficiency of folate in the U.S. population but may result from metabolic defects or other physiologic conditions affecting a small part of the population. These new data support FDA's decision to require that claims not imply that folate intake is the only recognized risk factor for neural tube defects.

## 7. Prevalence Statements

In § 101.79(c)(2)(i)(E), the agency proposed to require that the claim provide information that neural tube defects "while not widespread, are extremely significant." Because the affected population is few in number and not readily identifiable, FDA proposed to require that this information be disclosed to prevent women from being misled into believing that neural tube defects are very common birth defects, or that, lacking a personal or family history of such defects or other recognized risk factors, their risk of having a pregnancy affected with such a birth defect is very high.

37. The agency received a number of comments on the proposed prevalence statement. Some comments stated that the wording "while not widespread" was not clear, and one comment suggested use of "uncommon" rather than "while not widespread" in describing the prevalence of neural tube defects. One comment noted that statements indicating that neural tube defects had a low prevalence in the United States would discourage women from taking folic acid supplements because women would believe that the health claim is not applicable to them, and they would be misled into not taking the health claim seriously. One comment noted that there is no standard for the proposed term "not widespread." One comment noted that because the behavior intended to result from authorization of the health claim was to have women consume more folic acid, qualifiers regarding prevalence of the condition had no educational benefit. One comment, noting that statements regarding the extent of the disease-related conditions were optional in other approved health claims, and that the rarity of spina bifida and related birth defects is obvious to virtually all consumers, urged the agency to make prevalence statements optional in the folate/neural tube defect claim.

The Folic Acid Subcommittee also commented on issues of prevalence and demographics of neural tube defects at all of its meetings (e.g., Ref. 8). The Folic Acid Subcommittee discussed the decline in the rate of neural tube defects from a high in Boston in the 1930's of 5 per 1,000 births to the current overall U.S. rate of about 0.6 per 1,000 births (i.e., about 2,500 cases/year in the United States). In addressing the prevalence of neural tube defects among different ethnic groups, one Folic Acid Subcommittee member noted that African-American women have a rate lower than the overall U.S. rate, while Mexican-American women have a rate

about two and one-half times the national average. The participant also noted that there is about a two-fold higher rate among women in lower socio-economic groups than among those in higher socio-economic groups (Ref. 8).

The agency has reviewed the comments that it received and agrees that use of the proposed wording "while not widespread" is not clear because it is not quantitative. The agency notes that even though the occurrence of neural tube defect-affected pregnancies is low, the population at risk may be quite large because about half of pregnancies are unplanned. Therefore, the agency concludes that a statement of prevalence is not a material fact in light of the other statements made in the claim. For this reason, the agency concludes that it is not necessary to require that the claim state that the prevalence of neural tube defects is low to ensure that the claim is not misleading. Therefore, the agency is deleting the requirement proposed in § 101.79(c)(2)(i)(E) and redesignating subsequent sections as discussed below and as shown in the codified language.

However, given the other comments cited above and its discussions with the Folic Acid Subcommittee, the agency does not agree that there would be no educational benefit from providing prevalence information in the health claim. The agency concludes, based on the comments above, that prevalence information can be useful to consumers because it can provide a context that increases understanding of how frequently neural tube defects actually occur among pregnancies in the U.S. population.

The agency recognizes that it has provided for inclusion, on an optional rather than required basis, in other authorized health claims of information on the number of people in the United States who have the health-related condition (e.g., see saturated fat and cardiovascular disease claim and dietary fiber and cancer claims). Thus, in response to the comments above, and consistent with other authorized health claims, FDA, in § 101.79(c)(3)(v), is authorizing the use of optional statements to provide the estimated numbers on an annual basis of neural tube defect births among live births to women in the general U.S. population. Currently, this estimate is 0.6 cases per 1,000 live births, or 6 cases per 10,000 live births, or about 2,500 cases among 4 million live births, or about 1 case per 1,600 live births. These estimates are based on information for the U.S. population from PHS. FDA finds, based on a review of how such statistics are

generally presented, that expressing this information as the estimated annual number of neural tube defects per a specified number of births (e.g., per 1,000 live births or per 10,000 live births) will help to make this information as useful as possible. Section 101.79(c)(3)(v) provides for use of these estimates unless more current estimates from PHS become available, in which case, the newer estimates may be used.

#### 8. Quantifying Risk Reduction

In § 101.79(c)(2)(i)(F), the agency proposed that the claim contain a statement that some women may reduce their risk of a neural tube defect-affected pregnancy by maintaining adequate folate intake during their childbearing years. Such a statement is consistent with the estimate provided in the PHS recommendation that about half of neural tube defects (i.e., about 1,250 annually) might be averted if all women of childbearing age in the United States who are capable of becoming pregnant consumed 0.4 mg of folate daily throughout their childbearing years. FDA tentatively concluded that such a statement is necessary to ensure that women do not conclude on the basis of the claim that adequate intake of folate will prevent all occurrences of neural tube defects. The agency also proposed in § 101.79(c)(2)(i)(F) that the claim not attribute any specific degree of reduction in risk of neural tube defects to maintaining an adequate folate intake throughout the childbearing years.

38. Several comments agreed with the agency that a specific degree of reduction in risk should not be stated in the health claim. Other comments noted that while occurrence of neural tube defects will be averted by only some women, the risk of occurrence will be reduced for the population. Other comments objected to the proposal to prohibit use of the PHS estimated percent risk reduction of 50 percent. Some comments argued that the 50 percent estimate should be stated because it was a scientific finding, and that failure to include this estimate could have a negative effect on how much effort women make to ensure that they have adequate folate intake. Another comment stated that the estimate of 50 percent reduction should be included because it is preferable for women to know the exact benefit of folic acid rather than to be informed that "some but not all women may benefit."

The agency disagrees with comments that the PHS estimate of 50 percent is a scientific finding and represents an exact benefit achievable by all women who consume adequate folate daily

throughout their childbearing years. The PHS recommendation states that the 50 percent estimate was derived from studies that associated recalled use of folic acid-containing multivitamins with reduced risk of neural tube defect-affected pregnancies and states that "the protective effect found in the studies of lower-dose folic acid, measured by the reduction in neural tube defect incidence, ranged from *none* to *substantial*" (Ref. 5) (emphasis added). The PHS recommendation also noted that:

It is expected that consumption of adequate folic acid will avert some, but not all, neural tube defects. The underlying causes of neural tube defects are not known. Thus, it is not known what proportion of neural tube defects will be averted by adequate folic acid consumption. From the available evidence, CDC estimates that there is the potential for averting 50 percent of cases that now occur. However, until further research is done, no firm estimate of this proportion will be available (Ref. 5).

The agency also notes that there may be minimal or no effect of periconceptional use of folate in areas of low prevalence or in areas where other factors are contributing to an increased prevalence. This observation is consistent with scientific evidence that shows that, in an area of low prevalence in the United States, women who consumed folate from multivitamins or fortified breakfast cereals did not have a lower risk of having a neural tube defect-affected pregnancy than did women who did not consume multivitamins or fortified breakfast cereals (Ref. 12; Mills et al.).

Thus, the estimate of a potential for a 50 percent reduction in neural tube defect-affected pregnancies, if all women consumed adequate folate throughout their childbearing years, is not a scientific finding and may not be applicable to estimating potential risk reduction in areas of low prevalence. The agency notes further that the estimate of 50 percent is not applicable to risk reduction that might be experienced by individual women, whose personal risk factors are not fully understood. In addition, the estimated proportion may change with the availability of new scientific data and information. The agency recognizes, however, that manufacturers may wish to use the PHS recommendation, including the estimate of the potential for a 50 percent reduction in the incidence of neural tube defects, as labeling for folate-containing products. The agency also notes that there is considerable potential for making a misleading claim if such information is not presented in an accurate context.

The agency has concluded that an estimate of potential risk reduction can be included in the health claim because it may help some consumers better understand the potential population-based impact on neural tube defect-affected pregnancies if all women consumed adequate folate throughout their childbearing years. Therefore, FDA is providing in § 101.79(c)(2)(i)(E) that population-based estimates of risk reduction may be included in the claim so long as the claim makes clear that the estimate does not reflect risk reduction that may be experienced by individual women. Provision of such information will reduce the likelihood of women being misled that adequate folate intake will prevent an occurrence of a neural tube defect-affected pregnancy.

The agency has revised § 101.79(b)(3) to provide information from the PHS recommendation that explains how the estimate of a potential for reduction in incidence of neural tube defects of 50 percent was derived and provides the context in which the estimate can be understood by individual women.

FDA has also redesignated proposed § 101.79(c)(2)(i)(F) as § 101.79(c)(2)(i)(E) and revised this section to remove the prohibition against use of the PHS estimate. Section 101.79(c)(2)(i)(E) includes reference to new § 101.79(c)(3)(vi) which provides for optional inclusion of statements about population-based estimates of risk reduction. The requirement that claims state that some women may reduce their risk of a neural tube defect-affected pregnancy through adequate intake of folate throughout their childbearing years is retained in § 101.79(c)(2)(i)(E).

New § 101.79(c)(3)(vi) states that an estimate of the reduction in the number of neural tube defect-affected births that might occur in the United States if all women consumed adequate folate throughout the childbearing years (i.e., 50 percent) may be included in the claim if such an estimate is accompanied by information that states that it is a population-based estimate and does not reflect reduction in risk that may be experienced by individual women. New § 101.79(c)(3)(vi) also provides for use in the claim of information in revised § 101.79(b)(3).

#### 9. Optional Health Claim Information

In § 101.79(c)(3)(i), the agency proposed to permit manufacturers, in addition to including the fact that neural tube defects have many causes, to specifically identify risk factors for neural tube defects. The agency stated that specific examples of other risk factors include a personal history of such a defect, maternal diabetes

mellitus, use of the antiepileptic drug valproic acid, maternal febrile illness, or a close relative with a neural tube defect (§ 101.79(b)(1) and (b)(2)). The agency requested comments on whether such additional information would be useful to consumers.

#### a. Identifying other risk factors.

39. Some comments expressed the opinion that most of the optional information was helpful, while others stated that there was no educational value in identifying the multifactorial nature of neural tube defects, and that women cannot control other risk factors.

The agency disagrees with the comments that stated that identification of other risk factors would not be helpful to women. Certain conditions, such as diabetes mellitus, are known to increase a woman's risk of a neural tube defect-affected pregnancy. Identification of these risks in the claim may serve to alert some women to their higher risk and encourage them to seek advice from their health care providers before becoming pregnant.

The agency is providing in § 101.79(c)(3)(i) for the inclusion of optional information in the claim. Information in § 101.79(b)(1) or (b)(2) or drawn from other parts of § 101.79(c)(3) may be included in the claim. Use by manufacturers of factors listed in the regulation will ensure that claims will only include scientifically-based information and will not include information that has not been well-documented (e.g., "Birth defects of the brain or spinal cord may have many causes, such as exposure to pesticides \* \* \*").

b. *Consult a physician.* In § 101.79(c)(3)(iii), the agency proposed that a claim could include a statement that women with a history of a neural tube defect pregnancy should consult their physicians or health care providers before becoming pregnant. The agency tentatively concluded that such a statement would encourage such women to obtain medical guidance and thereby decrease their risk of a recurrence of a neural tube defect-affected pregnancy. The available data show that women with a history of a neural tube defect-affected pregnancy are at very high risk of another affected pregnancy (e.g., risk of a recurrence of a neural tube defect pregnancy is significantly greater than risk of an occurrence of this birth defect). The agency requested comments on whether provision of such information would be helpful to consumers.

40. The agency received several comments on this proposed optional information. All comments that addressed this issue recommended that

it be broadened to include all women rather than only those with a personal history of a neural tube defect-affected pregnancy. Comments stated that prenatal care was critical for all women and suggested that health claims should include a statement that all women planning a pregnancy should consult a physician or health care provider for information about adequate diets for their and their babies' health. Several comments suggested that such a statement be mandatory rather than optional.

FDA does not believe that it is appropriate, in general, for health claims to bear statements concerning the need to seek medical advice for treating the disease or health-related condition mentioned in the claim. The agency is concerned that the appearance of a statement concerning the treatment of a disease on the label of a food could mislead some consumers to believe that the food possesses therapeutic value for an existing disease or health-related condition (58 FR 2478 at 2514).

The agency originally proposed such a statement regarding women at recurrent risk of a neural tube defect-affected pregnancy because their risk of recurrence is very high, and because a specific recommendation from PHS has been made to such women when they are planning a pregnancy (i.e., they are advised to take 4 mg folic acid daily under a physician's supervision; Ref. 52).

Because all comments favored broadening the advice to include all women, and because the agency recognizes that it is important for all women to consult a health care provider before becoming pregnant, the agency is persuaded to modify § 101.79(c)(3)(iii) as suggested in the comments and to provide for claims to include, in addition to a statement regarding women at recurrent risk of a neural tube defect, a statement that all women should consult a health care provider before becoming pregnant (e.g., "Women, including those with a history of a neural tube defect pregnancy, should consult their health care provider when planning a pregnancy.").

However, because the length of claims has been consistently a concern of the comments, the agency is not persuaded that the information provided for in § 101.79(c)(3)(iii) should be required in all health claims, as suggested by one comment above. 10. Model Health Claims

FDA provided several model claims in the proposal that contained the elements described in its proposal. The agency included these model claims to

assist manufacturers in formulating appropriate claims.

*a. Toll-free number, pregnancy information symbol.*

41. Several comments stated that less detailed model claims were needed and proposed that the agency establish a toll-free 800 number through which women could obtain more information or recommended that the agency devise a uniform pregnancy information symbol for food labels that would alert women to look for products that bear the symbol.

The agency agrees that educational information is of great importance in increasing awareness among women of the need for adequate nutrition, including adequate folate intake, during their childbearing years. The agency is considering how best to evaluate consumer understanding of the health claim and is working with other PHS agencies to develop strategies to implement the PHS recommendation on folate intake.

With respect to the use of a pregnancy information symbol, the agency noted above that many pregnancies are unplanned, and for this reason, women need to be informed of the need for adequate nutrition throughout their childbearing years. While a pregnancy symbol might draw the attention of women who are already pregnant or who might be planning a pregnancy, it may not be helpful to women whose pregnancies are unplanned or to women whose pregnancies are too far advanced for folate intake to alter their risk of giving birth to a neural tube defect-affected infant. Such a symbol may also discourage other women from using the product because they do not think they will become pregnant.

The agency also notes that many of the foods that will bear the health claim will be consumed by the general population, and the appearance of a pregnancy symbol on the label might be incorrectly interpreted by some consumers to mean that the product is specifically intended for use in pregnancy.

For these reasons, the agency is not persuaded to use a pregnancy symbol with the health claim.

*b. General comments.*

42. Many comments criticized the length of the model claims and their required components. Comments stated that the model messages were too lengthy and complex and unwieldy, and that therefore manufacturers would be disinclined to use them. Other comments noted that the claims included unnecessary disclosures and requested that FDA remove the requirements relating to the

multifactorial nature of neural tube defects, sources of folate other than dietary supplements, and the caution statement. Several comments, stating that the model claims were overly focused on foods, urged the agency to develop a condensed claim for dietary supplements and suggested that such a claim should not need to identify other sources of folate or state a maximum daily limit on intake.

Another comment noted that in formulating the claim, the agency should be guided by the need to communicate the benefits of increased folate intake from food sources or dietary supplements, and that the message must also convey proper cautions, including the fact that increased folate intake will not prevent all birth defects or even all neural tube defects. Several comments praised portions of the model claims that required disclosure of the multifactorial nature of neural tube defects and the inclusion of information regarding sources of folate. One comment recommended that claims use the information in the PHS recommendation, including the warning statement, as closely as possible. Several comments noted that the model claims were not educationally strong enough, while others recognized the problem of providing the guidance that needs to be included in the claim without having the claim become so long as to be unusable. Some comments provided examples of shorter claims that they proposed as more appropriate than the agency's model claims.

As discussed in the proposal and elsewhere in this final rule, certain information is needed in the health claim, whether for conventional foods or for dietary supplements, for such claims to be truthful, scientifically valid, and not misleading to segments of the population that are not at high risk of having a neural tube defect-affected pregnancy or for whom no link between folate intake and risk of neural tube defect-affected pregnancies has been established.

The agency has addressed the issues of mandatory requirements relating to the multifactorial nature of neural tube defects, sources of folate other than dietary supplements, and the caution statement in response to comments 36, 21, and 32, respectively. The agency disagrees that all of these elements should be removed. Specifically, the agency has discussed in response to comment 36 why claims shall not imply that folate intake is the only risk factor for neural tube defects. In response to comments 28 through 34, the agency explained why a caution statement is

necessary, as well as its reasoning in limiting the requirement for such a statement to very narrow circumstances. The agency in response to comments has dropped the requirement that sources of folate be identified in the claim and instead has provided for optional inclusion of such information.

The agency also disagrees that its proposed model claims were overly focused on foods because each of the proposed claims specifically identified sources of folate as fruits, vegetables, whole grain products, fortified cereals, and dietary supplements.

The agency rejects the comments that urged it to develop a condensed claim for dietary supplements and not identify a safe upper limit of daily intake. Throughout its responses to the comments it received, the agency has been even-handed in considering conventional foods and dietary supplements (comments 29 and 32, above). Since increased folate intake is what is of importance, and since a variety of dietary sources of folate are available, it would be inconsistent with the available evidence for the agency to set different requirements for claims on dietary supplements than for claims on conventional foods.

Thus, the agency, in developing this final rule, has been guided by the need to communicate the effects on the risk of neural tube defects of increased folate intake while providing sufficient cautions to prevent claims from being misleading and to ensure that they are scientifically valid.

FDA has modified the model claims to reflect the changes that it has made in § 101.79 in response to the comments. The agency has sought to illustrate in the model claims that it is possible to fully comply with § 101.79 and still produce a claim that uses less than 30 words (see Examples 1 and 2 in § 101.79(d)). The agency also notes that in response to the petition from the National Food Processors Association, mentioned above, it is exploring the possibility of permitting a shortened version of the claim to appear on the front panel of the food label as long as the full claim appears on the label. FDA is considering how this can be accomplished while still ensuring that there is full compliance with section 403 (a) and (r) of the act. FDA anticipates publishing a proposal on these matters in the near future.

### III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore,

neither an environmental assessment nor an environmental impact statement is required.

#### IV. Economic Impact

FDA has examined the impacts of this final rule to authorize the use on the labels and in the labeling of conventional food and dietary supplements of health claims on the relationship between adequate folate intake and risk of neural tube birth defects as required by Executive Order 12866 and the Regulatory Flexibility Act. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts and equity). The Regulatory Flexibility Act (Pub. L. 96-654) requires analyzing options for regulatory relief for small businesses. FDA finds that this final rule is not a significant regulatory action as defined by Executive Order 12866. In compliance with the Regulatory Flexibility Act, the agency certifies that the final rule will not have a significant impact on a substantial number of small businesses.

On October 14, 1993, FDA published an analysis of the economic impact of the proposed rule under the previous Executive Order (E.O. 12291). In that analysis, the agency stated that folate health claims may result in increased demand for products containing folate, and that an increase in consumption of products containing folate is likely to result in health benefits in terms of fewer neural tube defects. The agency also stated that there would be no costs associated with folate health claims as use of these claims is voluntary.

The agency concluded that it was not able to estimate the number of products that will bear health claims, or the effect that folate health claims will have on consumer demand for products containing folate, and requested comments. As mentioned previously, the agency received nearly 100 comments in response to the proposed rule on health claims for folate and neural tube defects. None of the comments provided information that would alter the agency's economic impact conclusion.

#### V. Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et. seq.).

#### VI. References

The following information has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday.

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- List of Subjects in 21 CFR Part 101
- Food labeling, Nutrition, Reporting and recordkeeping requirements.
- Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

## PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.9 *Nutrition labeling of food* is amended in paragraph (c)(8)(v) by revising the entry for folate to read as follows:

### § 101.9 Nutrition labeling of food.

(c) \* \* \*

(8) \* \* \*

(v) \* \* \*

Folate—either folic acid or folacin may be used.

\* \* \* \* \*

### § 101.36 [Amended]

3. Section 101.36 *Nutrition labeling of dietary supplements of vitamins and minerals* is amended in paragraph (b)(3)(v) by removing the words "folate (folacin)," and by adding in their place the words "folate—either folic acid or folacin may be used."

4. Section 101.79 is revised to read as follows:

### § 101.79 Health claims: Folate and neural tube defects.

(a) *Relationship between folate and neural tube defects—(1) Definition.* Neural tube defects are serious birth defects of the brain or spinal cord that can result in infant mortality or serious disability. The birth defects anencephaly and spina bifida are the most common forms of neural tube defects and account for about 90 percent of these defects. These defects result from failure of closure of the covering of the brain or spinal cord during early embryonic development. Because the neural tube forms and closes during early pregnancy, the defect may occur before a woman realizes that she is pregnant.

(2) *Relationship.* The available data show that diets adequate in folate may reduce the risk of neural tube defects. The strongest evidence for this relationship comes from an intervention study by the Medical Research Council of the United Kingdom that showed that women at risk of recurrence of a neural tube defect pregnancy who consumed a supplement containing 4 milligrams (mg) (4,000 micrograms (mcg)) folic acid daily before conception and continuing into early pregnancy had a reduced risk of having a child with a neural tube defect. (Products containing this level of folic acid are drugs). In addition, based on its review of a Hungarian intervention trial that reported periconceptional use of a multivitamin and multimineral preparation containing 800 mcg (0.8 mg) of folic acid, and its review of the observational studies that reported periconceptional use of multivitamins containing 0 to 1,000 mcg of folic acid, the Food and Drug Administration concluded that most of these studies had results consistent with the conclusion that folate, at levels attainable in usual diets, may reduce the risk of neural tube defects.

(b) *Significance of folate—(1) Public health concern.* Neural tube defects



occur in approximately 0.6 of 1,000 live births in the United States (i.e., approximately 6 of 10,000 live births; about 2,500 cases among 4 million live births annually). Neural tube defects are believed to be caused by many factors. The single greatest risk factor for a neural tube defect-affected pregnancy is a personal or family history of a pregnancy affected with a such a defect. However, about 90 percent of infants with a neural tube defect are born to women who do not have a family history of these defects. The available evidence shows that diets adequate in folate may reduce the risk of neural tube defects but not of other birth defects.

(2) *Populations at risk.* Prevalence rates for neural tube defects have been reported to vary with a wide range of factors including genetics, geography, socioeconomic status, maternal birth cohort, month of conception, race, nutrition, and maternal health, including maternal age and reproductive history. Women with a close relative (i.e., sibling, niece, nephew) with a neural tube defect, those with insulin-dependent diabetes mellitus, and women with seizure disorders who are being treated with valproic acid or carbamazepine are at significantly increased risk compared with women without these characteristics. Rates for neural tube defects vary within the United States, with lower rates observed on the west coast than on the east coast.

(3) *Those who may benefit.* Based on a synthesis of information from several studies, including those which used multivitamins containing folic acid at a daily dose level of  $\geq 400$  mcg ( $\leq 0.4$  mg), the Public Health Service has inferred that folate alone at levels of 400 mcg (0.4 mg) per day may reduce the risk of neural tube defects. The protective effect found in studies of lower dose folate measured by the reduction in neural tube defect incidence, ranges from none to substantial; a reasonable estimate of the expected reduction in the United States is 50 percent. It is expected that consumption of adequate folate will avert some, but not all, neural tube defects. The underlying causes of neural tube defects are not known. Thus, it is not known what proportion of neural tube defects will be averted by adequate folate consumption. From the available evidence, the Public Health Service estimates that there is the potential for averting 50 percent of cases that now occur (i.e., about 1,250 cases annually). However, until further research is done, no firm estimate of this proportion will be available.

(c) *Requirements.* The label or labeling of food may contain a folate/

neural tube defect health claim provided that:

(1) *General requirements.* The health claim for a food meets all of the general requirements of § 101.14 for health claims, except that a food may qualify to bear the health claim if it meets the definition of the term "good source."

(2) *Specific requirements—(i) Nature of the claim—(A) Relationship.* A health claim that women who are capable of becoming pregnant and who consume adequate amounts of folate daily during their childbearing years may reduce their risk of having a pregnancy affected by spina bifida or other neural tube defects may be made on the label or labeling of food provided that:

(B) *Specifying the nutrient.* In specifying the nutrient, the claim shall use the terms "folate," "folic acid," "folacin," "folate, a B vitamin," "folic acid, a B vitamin," or "folacin, a B vitamin."

(C) *Specifying the condition.* In specifying the health-related condition, the claim shall identify the birth defects as "neural tube defects," "birth defects spina bifida or anencephaly," "birth defects of the brain or spinal cord anencephaly or spina bifida," "spina bifida and anencephaly, birth defects of the brain or spinal cord," "birth defects of the brain or spinal cord;" or "brain or spinal cord birth defects."

(D) *Multifactorial nature.* The claim shall not imply that folate intake is the only recognized risk factor for neural tube defects.

(E) *Reduction in risk.* The claim shall not attribute any specific degree of reduction in risk of neural tube defects from maintaining an adequate folate intake throughout the childbearing years. The claim shall state that some women may reduce their risk of a neural tube defect pregnancy by maintaining adequate intakes of folate during their childbearing years. Optional statements about population-based estimates of risk reduction may be made in accordance with paragraph (c)(3)(vi) of this section.

(F) *Safe upper limit of daily intake.* Claims on foods that contain more than 100 percent of the Daily Value (DV) (400 mcg) when labeled for use by adults and children 4 or more years of age, or 800 mcg when labeled for use by pregnant or lactating women) shall identify the safe upper limit of daily intake with respect to the DV. The safe upper limit of daily intake value of 1,000 mcg (1 mg) may be included in parentheses.

(G) *The claim.* The claim shall not state that a specified amount of folate per serving from one source is more effective in reducing the risk of neural tube defects than a lower amount per serving from another source.

(H) The claim shall state that folate needs to be consumed as part of a healthful diet.

(ii) *Nature of the food—(A) Requirements.* The food shall meet or exceed the requirements for a "good source" of folate as defined in § 101.54;

(B) *Dietary supplements.* Dietary supplements shall meet the United States Pharmacopeia (USP) standards for disintegration and dissolution, except that if there are no applicable USP standards, the folate in the dietary supplement shall be shown to be bioavailable under the conditions of use stated on the product label.

(iii) *Limitation.* The claim shall not be made on foods that contain more than 100 percent of the RDI for vitamin A as retinol or preformed vitamin A or vitamin D per serving or per unit.

(iv) *Nutrition labeling.* The nutrition label shall include information about the amount of folate in the food. This information shall be declared after the declaration for iron if only the levels of vitamin A, vitamin C, calcium, and iron are provided, or in accordance with § 101.9 (c)(8) and (c)(9) if other optional vitamins or minerals are declared.

(3) *Optional information—(i) Risk factors.* The claim may specifically identify risk factors for neural tube defects. Where such information is provided, it may consist of statements from § 101.79(b)(1) or (b)(2) (e.g., Women at increased risk include those with a personal history of a neural tube defect-affected pregnancy, those with a close relative (i.e., sibling, niece, nephew) with a neural tube defect; those with insulin-dependent diabetes mellitus; those with seizure disorders who are being treated with valproic acid or carbamazepine) or from other parts of this paragraph (c)(3)(i).

(ii) *Relationship between folate and neural tube defects.* The claim may include statements from paragraphs (a) and (b) of this section that summarize the relationship between folate and neural tube defects and the significance of the relationship except for information specifically prohibited from the claim.

(iii) *Personal history of a neural tube defect-affected pregnancy.* The claim may state that women with a history of a neural tube defect pregnancy should consult their physicians or health care providers before becoming pregnant. If such a statement is provided, the claim shall also state that all women should consult a health care provider when planning a pregnancy.

(iv) *Daily value.* The claim may identify 100 percent of the DV (100% DV; 400 mcg) for folate as the target intake goal.

(v) *Prevalence*. The claim may provide estimates, expressed on an annual basis, of the number of neural tube defect-affected births among live births in the United States. Current estimates are provided in § 101.79(b)(1), and are approximately 6 of 10,000 live births annually (i.e., about 2,500 cases among 4 million live births annually). Data provided in § 101.79(b)(1) shall be used, unless more current estimates from the U.S. Public Health Service are available, in which case the latter may be cited.

(vi) *Reduction in risk*. An estimate of the reduction in the number of neural tube defect-affected births that might occur in the United States if all women consumed adequate folate throughout their childbearing years may be included in the claim. Information contained in paragraph (b)(3) of this section may be used. If such an estimate (i.e., 50 percent) is provided, the estimate shall be accompanied by additional information that states that the estimate is population-based and that it does not reflect risk reduction that may be experienced by individual women.

(vii) *Diets adequate in folate*. The claim may identify diets adequate in folate by using phrases such as "Sources of folate include fruits, vegetables, whole grain products, fortified cereals, and dietary supplements." or "Adequate amounts of folate can be obtained from diets rich in fruits, dark green leafy vegetables, legumes, whole grain products, fortified cereals, or dietary supplements." or "Adequate amounts of folate can be obtained from diets rich in fruits, including citrus fruits and juices, vegetables, including dark green leafy vegetables, legumes, whole grain products, including breads, rice, and pasta, fortified cereals, or a dietary supplement."

(d) *Model health claims*. The following are examples of model health claims that may be used in food labeling to describe the relationship between folate and neural tube defects:

(1) *Examples 1 and 2*. Model health claims appropriate for foods containing 100 percent or less of the DV for folate per serving or per unit (general population). The examples contain only the required elements:

(i) Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect.

(ii) Adequate folate in healthful diets may reduce a woman's risk of having a child with a brain or spinal cord birth defect.

(2) *Example 3*. Model health claim appropriate for foods containing 100

percent or less of the DV for folate per serving or per unit. The example contains all required elements plus optional information: Women who consume healthful diets with adequate folate throughout their childbearing years may reduce their risk of having a child with a birth defect of the brain or spinal cord. Sources of folate include fruits, vegetables, whole grain products, fortified cereals, and dietary supplements.

(3) *Example 4*. Model health claim appropriate for foods intended for use by the general population and containing more than 100 percent of the DV of folate per serving or per unit: Women who consume healthful diets with adequate folate may reduce their risk of having a child with birth defects of the brain or spinal cord. Folate intake should not exceed 250% of the DV (1,000 mcg).

Dated: February 26, 1996.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 96-5013 Filed 2-29-96; 1:12 pm]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 136, 137, and 139

[Docket No. 91N-100S]

RIN 0910-AA19

#### Food Standards: Amendment of Standards of Identity For Enriched Grain Products to Require Addition of Folic Acid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the standards of identity for several enriched grain products and, by cross-reference, the standards of identity for enriched bromated flour, enriched vegetable macaroni, and enriched vegetable noodle products, to require the addition of folic acid. The agency is requiring that these products be fortified with folic acid at levels ranging from 0.43 milligrams (mg) to 1.4 mg per pound (mg/lb) or 95 micrograms (µg) to 309 µg/100 grams (g), of product. These values are based on a fortification level of 140 µg/100 g (0.635 mg/lb) of the cereal grain product. This action is

being taken to help women of childbearing age to reduce their risk of having a pregnancy affected with spina bifida or other neural tube defects (NTD's) and to comply with the recommendation of the U.S. Public Health Service (PHS) that they consume at least 0.4 mg (400 µg) of folic acid daily. This action also responds to a citizen petition submitted by Glenn Scott.

**EFFECTIVE DATE:** January 1, 1998.

#### FOR FURTHER INFORMATION CONTACT:

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#### SUPPLEMENTARY INFORMATION:

##### I. Background

Recent estimates state that there are approximately 4,000 pregnancies each year, including 2,500 live births, that are affected by spina bifida and other neural tube defects. In September 1992, PHS recommended that all women of childbearing age in the United States consume 0.4 mg (400 µg) of folic acid daily to reduce their risk of having a pregnancy affected with spina bifida or other NTD's (Ref. 1). Furthermore, PHS identified several possible approaches by which folate intake by the target population could be increased. These approaches included: (1) Improvement of dietary habits, (2) fortification of the U.S. food supply, and (3) daily use of folic acid supplements by women throughout their childbearing years. However, the PHS recommendation cautioned against daily intakes of folate above 1 mg. A recognized adverse effect of high intakes of folate is a masking of the anemia of vitamin B12 deficiency, allowing the neurologic damage to progress untreated. PHS noted that care should be taken to keep total folate consumption at less than 1 mg (1,000 µg)/day, except under the supervision of a physician (Ref. 1).

Following publication of the PHS recommendation, FDA convened a Folic Acid Subcommittee from its Food Advisory Committee (hereinafter referred to as the Folic Acid Subcommittee) to consider some of the issues raised by the recommendation. After consideration debate, the Folic Acid Subcommittee identified several approaches that might assist women of childbearing age to increase their daily folate intake. These approaches included: (1) Development of a fortification program such that 90 percent of women of childbearing age could receive at least 400 µg per day from all sources, while preventing

excessively high folate intakes by nontarget groups; (2) appropriate labeling of foods, including dietary supplements; and (3) implementation of an educational program directed primarily at women of childbearing age that emphasizes the importance of folate intake before pregnancy, and continuing into early pregnancy and its potential effect on reducing the incidence of NTD's. (For a detailed discussion of the issues and concerns raised by the Folic Acid Subcommittee please refer to the Health Claims proposed rule (58 FR 23254 at 23256) and the final rule authorizing a health claim about the relationship between folate and neural tube defects (hereinafter referred to as the claims final rule) published elsewhere in this issue of the Federal Register.)

After considering the suggestions of PHS and the Folic Acid Subcommittee, FDA tentatively concluded that development and implementation of a fortification program for the addition of folic acid to the food supply could be an effective part of an overall plan to increase the folate intake of women of childbearing age to assist them in reducing their risk of having a NTD-affected pregnancy. Food fortification, as noted by the Folic Acid Subcommittee and expert speakers who testified before the Folic Acid Subcommittee, has the advantage of reaching a great number of women in the target population before conception and during early pregnancy. It also has the advantage of providing folic acid in a continuous and passive manner and, thus, represents a potentially effective means for improving the folate nutriture of women throughout their childbearing years. However, fortification must be controlled to ensure that daily intake of folate by the target population, as well as by the general population, is no more than 1 mg.

The issues raised by a fortification program were highlighted for the agency in the Federal Register of October 14, 1993 (58 FR 53254), in a document entitled "Food Labeling: Health Claims and Label Statements; Folate and Neural Tube Defects," (hereinafter referred to as the folic acid health claims proposal) when it proposed to authorize a health claim about the relationship between folate and the risk of neural tube birth defects on the labels or in the labeling of foods and dietary supplements. In the folic acid health claims proposal (58 FR 53254 at 53270), FDA acknowledged that authorizing a health claim on folate and NTD's would create the likelihood that manufacturers would fortify their products with folic acid so that they could qualify to bear the claim, thereby

increasing the possibility of uncontrolled fortification of the food supply. Consequently, FDA said that any fortification program that it adopted must be consistent with a safe range of intake for all population groups and yet be capable of maximizing the folate intakes of the target population within this safe range.

The options that FDA considered for providing folic acid to women of childbearing age through food fortification included the addition of folic acid to cereal-grain products, fruit juices, and dairy products. In weighing these options, FDA considered the effects of the inclusion of folic acid in breakfast cereals and in dietary supplements. The agency's decision to factor the amount of folic acid supplied by breakfast cereals and supplements in its estimates of the effects of fortification is fully discussed in the folic acid health claims proposal (58 FR 53254 at 53276).

In determining the appropriate levels of fortification with folic acid, the agency used the U.S. Department of Agriculture's (USDA's) 1987 to 1988 national food consumption data (Ref. 2) to estimate the daily intake of folate for the target population, as well as for the general population, with fortification at different levels for cereal-grain products, dairy products, and juices. The agency estimated the effects of fortification using three values: 70, 140, and 350 µg of folic acid/100 g of cereal-grain product. As discussed in the folic acid health claims proposal, the value of 70 µg/100 g (0.317 µg/lb) is the amount recommended in 1974 by the Food and Nutrition Board, National Research Council, National Academy of Sciences, and would restore the folate lost in the milling of cereal-grain products (Ref. 3). The value of 140 µg/100 g is twice that amount, and 350 µg/100 g is five times that amount.

FDA's analysis showed that when fortification included fruit juices and dairy products in addition to cereal-grain products, ready-to-eat breakfast cereals, and dietary supplements, intakes by consumers in some nontarget groups exceeded 1 mg/day even at the lowest level of fortification. However, when fortification is limited to cereal-grain products at levels of 70 µg/100 g or 140 µg/100 g, estimates of daily intakes remained below 1 mg/100 g. At fortification levels of 350 µg/100 g, FDA estimated the daily intake to reach levels of 1,220 µg/day, which exceeds the recommended safe upper limit.

The agency also estimated the daily intake of folate for consumers who follow Federal government dietary guidance, such as the U.S. Dietary Guidelines and the DHHS/USDA Food

Guide Pyramid, and consume cereal-grain products fortified with folic acid, to determine whether these consumers will have daily intakes in excess of the recommended safe upper limit of 1 mg/day.

These estimates showed that consumers who followed even the low-end of recommendations from the USDA Food Guide Pyramid could, without supplement use, easily consume 420 µg or more of folate per day from cereal-grain products fortified with 70 µg/100 g. Further, such consumers' daily intake could triple if such products were fortified with 350 µg folic acid/100 g.

As a result of its analysis of fortification of several cereal-grain, dairy, and juice products, FDA tentatively determined that fortification should be limited to cereal-grain products and not extended to dairy products and fruit juices. The agency noted that intakes by very large segments of the general population could reach several milligrams per day if all of these foods were fortified with folic acid.

The agency also tentatively decided that the appropriate fortification level for cereal-grain products was 140 µg/100 g. Based on the results of its analysis, FDA determined that fortification of cereal-grain products with 140 µg/100 g, along with fortification of ready-to-eat breakfast cereals up to 100 µg/serving and dietary supplements up to 400 µg per unit or per serving, would provide increased intakes of folate for women in their childbearing years, while keeping daily intakes for the nontarget population within the recommended safe upper limit of approximately 1 mg/day. The agency noted that even with supplement use, 95th percentile intakes by adults 51+ years of age could reach 840 to 860 µg/day if these enriched cereal-grain products are fortified with 140 µg/100 g. While the agency recognized that this level approached the recommended safe upper limit and did not take into account likely underreporting biases regarding food intakes and underestimation of folate content of foods, it tentatively concluded that fortification of cereal-grain products with 140 µg/100 g folic acid was the most appropriate fortification level of the three levels analyzed.

In addition to estimating daily intakes of folate at the levels cited above, FDA reviewed the existing food additive regulation § 172.345 (21 CFR 172.345) governing the use of folic acid to determine whether the regulation was adequate to ensure that addition of folic acid to foods would be consistent with

the fortification proposals discussed above. As a result of its review, FDA recognized that the existing regulation lacked the guidance necessary for manufacturers to decide which foods are appropriate for fortification, and the levels at which folic acid can be added. More importantly, FDA realized that the regulation would not have limited the addition of folic acid to enriched cereal-grain products, breakfast cereals, and dietary supplements. In fact, the regulation as written would have permitted folic acid addition to virtually any food.

Thus, in the same issue of the Federal Register that the agency proposed to authorize a health claim about the relationship of folate and NTD's (58 FR 53254 at 53270), it published a proposal entitled "Food Additives Permitted for Direct Addition to Food for Human Consumption, Folic Acid (Folacin)" (58 FR 53312) (hereinafter referred to as the food additives proposal) to amend the food additive regulation to restrict the addition of folic acid to specific foods. In that document, FDA proposed, among other things, to establish a limitation on the addition of folic acid to breakfast cereals of 100 µg folic acid per serving, to retain current limitations (i.e., 400 µg/daily) on the use of folic acid in dietary supplements, and to permit the addition of folic acid to foods as authorized by the standards of identity. The agency tentatively concluded that such action was necessary to establish safe conditions of use for folic acid in the food supply and still assist the target population, women of childbearing age, to achieve the goal recommended by PHS that they consume at least 400 µg of folate per day.

Also, in the October 14, 1993, issue of the Federal Register, FDA published a proposal entitled "Food Standards: Amendment of the Standards of Identity for Enriched Grain Products to Require Addition of Folic Acid," (58 FR 53305) (hereinafter referred to as the standards of identity proposal) to amend the following standards of identity to require the addition of folic acid at a fortification level of 140 µg/100 g: enriched bread, rolls, and buns (§ 136.115 (21 CFR 136.115)); enriched flour (§ 137.165 (21 CFR 137.165)); enriched self-rising flour (§ 137.185 (21 CFR 137.185)); enriched corn grits (§ 137.235 (21 CFR 137.235)); enriched corn meals (§ 137.260 (21 CFR 137.260)); enriched farina (§ 137.305 (21 CFR 137.305)); enriched rice (§ 137.350 (21 CFR 137.350)); enriched macaroni products (§ 139.115 (21 CFR 139.115)); enriched nonfat milk macaroni products (§ 139.122 (21 CFR 139.122)); and

enriched noodle products (§ 139.155 (21 CFR 139.155)) and, by cross-reference, the standards of identity for enriched bromated flour (§ 137.160 (21 CFR 137.160)), enriched vegetable macaroni products (§ 139.135 (21 CFR 139.135)), and enriched vegetable noodle products (§ 139.165 (21 CFR 139.165)).

FDA received approximately 170 letters in response to its proposal to amend the standards of identity for enriched cereal-grain products to require folic acid fortification at 140 µg/100 g. Each letter contained one or more comments. The letters were from a wide range of sources, including individual members of FDA's Folic Acid Subcommittee and Food Advisory Committee, Federal and State Government agencies, a foreign government, health care organizations, academia, consumer organizations, medical professionals, consumers, industry, and industry trade associations. Some comments supported various provisions of the proposal. Other comments suggested modifications, revisions, or revocations of various provisions of the proposal. Some comments raised concerns that were more germane to issues discussed in the folic acid health claims and food additive proposals. These comments were forwarded to the appropriate dockets for response. Some comments raised issues that were outside the scope of this rulemaking and will not be addressed in this final rule. A summary of the relevant comments, the agency's responses to the comments, and a complete discussion of the agency's conclusions with respect to the fortification of enriched cereal-grain products follow.

## II. Comments and Agency Response

### A. Fortification

1. The majority of comments recognized the need to assist women of childbearing age to increase their daily intake of folate to reduce their risk of an NTD-affected pregnancy. Many of these comments agreed with the PHS' and Folic Acid Subcommittee's recommendations that fortification of the food supply is an appropriate approach to achieve this goal. Several comments, however, opposed the use of fortification as a mechanism to address this need. Some of the comments opposed fortification because of uncertainties in the efficacy data. These comments stated that the available data do not indicate what minimum level of folate is needed to effect a significant reduction in NTD's, and they argued that, therefore, the decision to fortify is premature. These comments suggested

that the agency wait until additional studies have been completed that better define the minimum level of folate needed to be effective or that identify other alternatives that would be effective in increasing the daily folate intake of the target population.

While FDA recognizes that there is some uncertainty in the literature as to the optimal intake of folate required to reduce the risk of NTD's, PHS, in examining the data from the available human studies, found the evidence sufficiently consistent to make its recommendation that all women capable of becoming pregnant should consume 400 µg folic acid daily. This target intake goal represents the best scientific judgment based on available data. It has also been supported by the Folic Acid Subcommittee.

Furthermore, PHS, the Folic Acid Subcommittee, as well as other medical experts, recommended food fortification as part of an overall program to improve the folate intake of women of childbearing age. This recommendation is based on the fact that 50 percent of pregnancies are unplanned, and that a large segment of women in the target group will not use folic acid supplements daily. Thus, a passive means of ensuring that these women have adequate folate intake is important. The comments that opposed fortification did not submit any data in support of their position. Thus, the agency has no basis to reject the recommendations of PHS and the Folic Acid Subcommittee to develop a folate fortification program to assist women of childbearing age in consuming at least 400 µg/day.

Although the agency is aware that there are several ongoing studies on the relationship between folate and NTD's, it has not been persuaded by the comments to wait until additional studies have been completed to determine what minimum level of folate intake is likely to be effective. The agency has confidence in the data that suggest that at intake levels of 400 µg/day, the incidence of NTD's can be reduced. Thus, the agency concludes that it would not be in the best interest of women in the target group to wait until these studies are completed and reviewed before implementing a program to assist them in increasing their daily intake of folate.

The evidence that is available supports the position that the consumption of folate plays an important role in reducing the risk of neural tube birth defects. Weighing this evidence and recognizing that the majority of women in the target population do not consume the levels of

folic acid recommended to reduce the risk of neural tube birth defects (Ref. 1), the agency concludes that it is appropriate to implement a fortification program at this time.

Further, the agency is concerned that without the limitations that it is adopting in this final rule, and in the final rule entitled "Food Additives Permitted for Direct Addition to Food for Human Consumption; Folic Acid (Folacin)" (hereinafter referred to as the food additives final rule) which is published elsewhere in this issue of the Federal Register, to control the addition of folic acid to the food supply, the authorization of the health claim about folate and NTD's may encourage overfortification of the U.S. food supply and increase the risk of overconsumption of folate. Because the current food additive regulation does not limit or specify the types of foods that can be fortified with folic acid, approval of the claim, without any other action by the agency, could encourage manufacturers to fortify a variety of foods to qualify the food for a health claim. Consequently, without proper control over the types of foods that can be fortified with folic acid, overfortification could result.

The amendment to the standards of identity for enriched cereal-grain products to require the addition of folic acid at specific levels will help to ensure that the addition of folic acid to the food supply is done in a safe, rational, and reasonable manner because it will limit the number of foods that can be fortified and limit the level of fortification. The levels of fortification established in this final rule, coupled with the provisions governing addition of folic acid to nonstandardized foods established in the food additives final rule, will meet the goal of increasing folate intake among women of childbearing age while keeping the daily consumption of folate below the safe upper limit of 1 mg/day.

2. Comments that opposed fortification asserted that consumers believe that fortification as proposed denies freedom of choice and control over daily folate intake and is, therefore, viewed as an attempt to medicate people without obtaining informed consent. These comments further asserted that fortification, as proposed, subjects them to the risk of overconsumption. As an alternative, these comments suggested that the effort to increase dietary folate intake in the target population focus on the use of dietary supplements because the amount of intake can be better controlled. They suggested that FDA work with other public health service

agencies to establish policy initiatives equivalent to those used by the food and dietary supplement industries to market their products.

The agency disagrees with these comments. The agency is providing for fortification with folic acid only in the standards of identity for enriched cereal-grain products. Unenriched cereal-grain products without folic acid will continue to be available. Consumers will be able to select foods made with the unenriched version of the product if they wish to avoid folic acid. Furthermore, the estimated daily intakes that will result from the level of fortification established in this final rule are well below the level of folic acid traditionally used to treat persons with folate deficiency. Therapeutic dosages of folic acid used for treatment of folate deficiency are generally in the range of 1 to 5 mg/day and are administered under the supervision of a physician. Therefore, the comments that suggest that fortification of enriched cereal-grain products is an attempt to medicate the U.S. population simply have no basis in fact.

Furthermore, the intakes that are likely to result from the level of fortification established in this final rule do not present a health concern to the general population, especially in conjunction with the provisions of the food additive final rule published elsewhere in this issue of the Federal Register. FDA has projected the total daily intake of folate that is likely to result from the levels of fortification that FDA is requiring and determined that it is well within the safe upper limit of intake. Moreover, cereal-grain products have a long history of being vehicles for improving the nutrient intake of the U.S. population. FDA requires the addition of niacin, thiamin, and riboflavin in the standards of identity for enriched cereal-grain products to improve the daily intake of these nutrients. Fortification of these products was instrumental in reducing the prevalence of diseases related to insufficient intake of these vitamins.

In response to the comments that suggested that FDA rely on the use of dietary supplements to increase daily folate intake, the agency notes that in requiring the fortification of enriched cereal-grain products, it is not discounting the use of dietary supplements to assist women in the target group to increase their daily folate intake. In fact, the agency included the use of dietary supplements in its estimates to determine the appropriate level for fortification of enriched cereal-grain products. However, the agency is not confident that the use of dietary

supplements alone will be sufficient to reach the target population when folate intake is critical (i.e., before and during the first 6 weeks of pregnancy).

During the first 6 weeks of pregnancy many women are not even aware that they are pregnant and would likely not be under the care of a physician. Thus, as stated in several comments, there would be no reason to expect the many women who do not normally take supplements daily to be motivated to change this behavior. Therefore, supplement use cannot be relied on as the sole source for increasing dietary folate intake. As discussed above, the use of fortification of cereal-grain products has the advantage of providing folic acid in a continuous and passive manner and, therefore, should be an effective means for improving the folate nutriture of women in their childbearing years.

3. A few comments opposed to fortification suggested that, as an alternative, FDA encourage women in the target group to increase their daily folate intake by increasing consumption of foods that naturally contain high levels of folate such as blackeye peas.

While FDA finds merit in the comments' suggestion to encourage women in the target group to increase their daily folate intake by increasing their consumption of foods naturally high in folate, the agency is not persuaded that such action makes food fortification unnecessary. The dietary guidance suggested by the comment can be used in conjunction with food fortification, as part of a program designed to help women in the target group to increase their daily folate consumption. A health claim about the relationship between folate and NTD's on a food that qualifies to bear the claim will contribute to such a program, regardless of whether the food naturally qualifies to bear the claim or qualifies on the basis of its fortification level. In addition, foods that naturally contain folate and qualify to bear a health or nutrient content claim are likely to be highlighted as a source of this nutrient. Such claims will encourage women in the target group to select these foods as a part of their diet.

Most significantly, however, given the value of adequate folate intake by women of childbearing age and given the value of a program that allows women to obtain adequate folate by simply consuming such staples as bread and rolls, FDA sees no reason not to require fortification of such foods, even though foods exist that are naturally high in folate.

4. Some comments opposed to fortification opined that fortification

would not assure physicians and health care professionals that their patients are obtaining adequate amounts of folate from the food supply because the bioavailability of folate in foods is 25 to 75 percent depending on the food.

As discussed in the folic acid health claims proposal, FDA considered several issues in developing its options for fortification. With respect to issues of bioavailability, FDA concluded that bioavailability cannot be meaningfully factored into fortification scenarios because issues of bioavailability are very complex, and no systematic data are available on many of the factors that affect bioavailability. Consequently, the estimates developed by FDA focused more on consumption patterns of various staple foods, and their availability and use in the U.S. food supply, than on the bioavailability of folic acid from a specific food.

The comment did not provide information to persuade the agency that the complexity associated with bioavailability would significantly reduce the effectiveness of food fortification as part of an overall effort to improve folate nutriture among women in the target group.

5. Two comments recommended revising the proposal to require the addition of vitamin B<sub>12</sub> in a one-to-one ratio with folic acid. The comments contended that doing so will not only prevent vitamin B<sub>12</sub> deficiency, but it will also prevent the masking effect that may be caused with high consumption of folate. One comment urged FDA to design research that will determine the safety and effectiveness of fortifying the food supply with vitamin B<sub>12</sub> along with folic acid because such fortification could eliminate the adverse effect of folate on vitamin B<sub>12</sub> deficiency.

The agency is not persuaded that the approach suggested by these comments addresses all of the safety concerns relating to persons with vitamin B<sub>12</sub> deficiencies. As fully discussed in the food additives final rule, FDA rejects this recommendation because the available data do not establish that requiring the addition of vitamin B<sub>12</sub> whenever folic acid is added will eliminate the safety concerns relating to persons with vitamin B<sub>12</sub> deficiencies that arise because of deficiencies in intrinsic factor (pernicious anemia) or other B<sub>12</sub>-related deficiencies.

6. Two comments opposed to fortification stated that FDA should take the same position with respect to folic acid fortification that it did when it decided not to fortify foods with iron in the 1970's because of the concern about iron storage diseases.

While the agency acknowledges that it considered taking a similar approach to increase the amount of iron provided by the diet when it proposed to double the amount of iron added to enriched cereal-grain products, the agency did not finalize that proposal because of significant safety concerns regarding the risk of iron storage diseases. Rather, the agency retained the existing level of iron fortification for cereal-grain products. The agency does not have similar safety concerns about the level of folic acid fortification that it is requiring in this final rule because it has concluded, based on a safety review (as fully discussed in the food additives proposal and final rule), that this required level is safe and will not result in overconsumption of folate.

#### *B. Covered Products*

7. Some comments stated that dietary consumption studies indicate that women of reproductive age are less likely than other groups to consume enriched cereal-grain products that conform to a standard of identity, and that, therefore, the use of such foods as a vehicle for folic acid fortification would not significantly affect the risk of NTD's. These comments argued that, instead, fortifying these foods will only increase the amount of daily folate intake among the nontarget groups.

In selecting cereal-grain products as vehicles for fortification, the agency started with the basic principle that fortification of staple products that are commonly consumed in significant amounts by virtually all members of the target population is most likely to result in increased intakes of a specific nutrient by the target population. Although the agency recognizes that current survey data suggest that consumption of enriched grain products may be somewhat lower in the target population than in other groups, these foods still are reported to be consumed on a daily basis by more than 90 percent of women of childbearing age (Ref. 4). In addition, data show that the difference between target and nontarget populations in consumption of other foods considered as fortification vehicles, such as dairy products and juices, is even greater (Ref. 4). Therefore, the other foods would be no more appropriate as fortification vehicles for maximizing folate intake by the target group, and yet maintaining safe consumption by nontarget groups, than cereal-grain products.

The agency notes that cereal-grain products were recommended by the Food and Nutrition Board in its 1974 report on food fortification as fortification vehicles because of the

patterns of consumption of these foods. In addition, enriched cereal-grain products have a long history of being successful vehicles for improving the nutriture of the U.S. population and for reducing the risk of nutrient deficiency diseases. Thus, the agency concludes that enriched cereal-grain products are an appropriate vehicle to increase daily folate intake among women of childbearing age. In fact, the estimates that FDA developed in evaluating options for folic acid fortification demonstrate that the addition of folic acid to enriched cereal-grain products, coupled with the addition of this nutrient to breakfast cereals and dietary supplements, will help to significantly increase the daily folate intake of women in the target group (see Table 7 of 58 FR 53254 at 53295)).

Furthermore, increasing awareness of the role of folate in reducing the risk of neural tube birth defects through the use of health claims and other educational initiatives should encourage women in the target group to increase their daily folate intake by consuming folate containing foods, including enriched cereal-grain products. Consumption of cereal-grain products is also likely to be influenced by current dietary guidelines that promote increased consumption of these foods.

8. Other comments requested that FDA permit the addition of folic acid to other cereal-grain products such as whole grain flours, breads, cereals, macaroni products, rice, and grits and not just the enriched cereal-grain foods that conform to a standard of identity. The comments argued that without these products being fortified, consumers may be encouraged to eat enriched refined grains instead of their whole grain counterparts and consequently follow dietary patterns that are inconsistent with current dietary guidelines to eat whole grain products.

FDA did not propose to provide for the addition of folic acid to whole grains or products from whole grains because, traditionally, these products are not enriched. Whole grain wheat products naturally contain higher levels of the B vitamins, including folate, because the germ and bran layer are not removed when the wheat kernel is processed. FDA's standards of identity for cracked wheat, crushed wheat, and whole wheat flour, in §§ 137.190, 137.195, and 137.200, respectively, state that the proportions of the natural constituents of such wheat, other than the moisture, remain unaltered by the manufacturing process. In establishing the standards of identity for the enriched cereal-grain products, the agency's initial goal was to

restore thiamin, niacin, and riboflavin, nutrients that are removed when the bran layer and germ are removed during the processing of wheat. Subsequently, the agency required the addition of iron to the enriched grain and also provided for the optional addition of other nutrients, such as calcium and vitamin D.

The estimates that the agency has relied on in selecting a fortification level of 140 µg/100 g considered only fortification of breakfast cereals, dietary supplements, and standardized enriched cereal grain products and did not include fortification of other nonstandardized or unenriched standardized cereal-grain products. Consequently, including such foods in the fortification program could result in a daily intake of folate that is above the safe upper limit of 1 mg/day. Thus, the agency is not persuaded by the comment that other cereal-grain products should be fortified with folic acid.

With regard to the concern raised in the comment that fortification of enriched cereal grain products may encourage consumers to choose these products over their whole grain counterparts, the comment did not provide any support for its concern. The decision to fortify enriched cereal grain products at the level of 140 µg/100 g is based on current dietary consumption patterns. The agency is not persuaded by the comments that the addition of folic acid will significantly change consumption patterns of the target population. There is no evidence that women will suddenly start consuming enriched products instead of whole grain foods. In fact, one reason the agency has decided to require the fortification of enriched cereal-grain products is to enable women of childbearing age to significantly increase their daily folate intake without changing their dietary habits. Finally, the agency notes that while current dietary recommendations do encourage increased consumption of whole grain foods, they also encourage consumption of all cereal-grain products.

9. One comment expressed concern that the agency's tentative decision to fortify cereal-grain products was unfair to the cereal-grain industry because it singled out one segment of industry to address a health concern. (The agency notes that the comment was not submitted by a member of the cereal grains industry.)

As discussed in the folic acid health claims proposal, FDA considered several options that included fortification of dairy products and juices before concluding that the most

appropriate option was to limit fortification to enriched cereal-grain products. Aside from the fact that these products have a long history of successful use as vehicles for increasing nutrient intake among U.S. consumers, consumption data and other relevant information reviewed by the agency show that these products are consumed routinely on a daily basis by 90 percent of women in the target group. Furthermore, some comments submitted to the docket by representatives of the cereal grains industry stated that, generally, these products can be easily fortified with folic acid. Therefore, FDA concludes that the enriched cereal-grain products are the appropriate foods for fortification, and that fortification of these products is not unfair to the industry.

#### *C. Fortification Level*

10. In the standards of identity proposal, FDA requested comments on whether the proposed fortification levels discussed for enriched cereal-grain products were appropriate. Comments responding to this issue were varied. Some comments that supported fortification of cereal-grain products stated that the proposed levels were too low to have any appreciable effect on reducing the risk of NTD's in the target population. One of these comments urged the agency to revise its proposal and require fortification at levels of at least 210 µg/100 g. However, the majority of these comments recommended that FDA require fortification of folic acid within the range of 250 to 350 µg/100 g. In support of their position, these comments contended that this range was well within limits for safety and should not mask the effects of vitamin B<sub>12</sub> deficiency. One comment further argued that at a fortification level of 350 µg/100 g, 95 percent of persons in the nontarget population would not consume more than 1 mg per day. One comment recommended 400 µg/100 g for cereal-grain products. This comment argued that fortification of enriched cereal-grain products should be at the same level as dietary supplements.

However, supplemental comments submitted by a majority of the organizations supporting a higher fortification level, stated that implementing fortification at a level of at least 140 µg/100 g will constitute a critically important step forward for the health of American children. Some of these comments further stated that fortification with at least 140 µg/100 g will be the most efficient and cost-effective approach to ensuring that women of childbearing age consume the

level of folic acid recommended to reduce the risk of having a neural tube defect affected pregnancy.

The agency agrees with the latter comments. As discussed in the folic acid health claims proposal (58 FR 53254 at 53279), fortification of cereal-grain products at 140 µg/100 g will produce a significant increase in daily folate intake, even for women who make food choices from the "low" range of the USDA Food Guide Pyramid and consume only 5 servings/day of cereal-grain products and 1 bowl of cereal containing a minimum of 100 µg of folic acid. From these sources alone, these women will consume about 320 µg of folic acid. Addition of a serving or two of vegetables, or of a serving of fruit, will provide them with a folate intake above 500 µg/day. Thus, fortification of cereal-grain products at 140 µg/100 g is an important step in assisting women of childbearing age achieve the PHS recommendation of consuming 400 µg.

However, if cereal-grain products were fortified at 350 µg/100 g, and the dietary choices indicated above were made, a "low" consumer would obtain 610 µg folic acid daily from these sources alone. Thus, at a fortification level of 350 µg/100 g a "high" consumer could reach intakes of folic acid of more than 1 mg/day from bread, noodle, rice, and pasta products alone. Additional consumption of breakfast cereals, fruits, vegetables, and a dietary supplement by "high" consumers could result in daily intakes of folate of about 2.5 mg/day, a level significantly above the safe upper limit of daily intake of 1 mg.

The comments supporting fortification of enriched cereal-grain products at levels above 140 µg/100 g did not provide any information to the agency that it had not considered in developing its proposed rules. Nor did the comments offer alternative fortification schemes that would allow addition of folic acid to enriched cereal-grain products at levels exceeding 140 µg/100 g yet limit the daily intake of folate to levels that are within the safe upper limit of 1 mg/day. Consequently, FDA disagrees with those comments that suggested that enriched cereal-grain products be fortified at levels of at least 210 µg/100 g. There simply is no evidence in the record that such a fortification program would keep folate intakes within the safe upper limit.

Accordingly, as proposed, the agency is requiring the addition of folic acid to enriched cereal grain products at a fortification level of 140 µg/100 g. FDA concludes that 140 µg/100 g is the maximum level of fortification of enriched cereal-grain products that would be safe for all groups.



Nonetheless, as the agency states in the final rule on the use of folic acid as a food additive, which is published elsewhere in this issue of the Federal Register, given the nature of the support for higher folic acid fortification levels in the comments, if evidence becomes available to support that there is a reasonable certainty of no harm at folate intakes above 1 mg/day, FDA would be willing to reconsider the fortification levels that it is adopting and to consider raising those levels.

11. Other comments opposed fortification at the proposed level of 140 µg/100 g on the grounds that it is too high. These comments asserted that such fortification may increase the risk of consuming folate at levels in excess of the safe upper limit of 1 mg/day in a substantial portion of the general population. Some of these comments suggested that FDA consider the lower fortification level of 70 µg/100 g in conjunction with an educational campaign that could still be effective in reducing the risk of NTD's yet not pose the risk of daily consumption of folate in excess of 1 mg/day.

In support of their position, some of these comments noted that the Food and Nutrition Board recommended the fortification of cereal-grain products at 70 µg/100 g to restore folate lost in the milling of cereal-grain products. Another comment supporting fortification at the restoration level contended that such action would permit additional restorations of nonstandardized foods such as breakfast cereals. One comment from a foreign government questioned FDA's decision to require folic acid fortification of all enriched cereal-grain products when the data do not clearly establish the effectiveness and safety of the proposed intervention program. However, the comment suggested support of the Food and Nutrition Board's 1974 proposal for cereal grain fortification, i.e., fortification with folic acid at 70 µg/100 g.

In the standards of identity proposal, FDA tentatively concluded that fortification of cereal-grain products with 140 µg/100 g folic acid was the most appropriate fortification level of the three levels analyzed to ensure that folate intakes by the target population would increase. The comments have not persuaded the agency that a fortification level of 70 µg/100 g could be as effective in assisting women in the target population to achieve the PHS recommended daily intake of 400 µg. In fact, at a fortification level of 70 µg/100 g, the estimated daily folate intake by "low" consumers among women of childbearing age is not likely to reach

the PHS recommended levels of 400 µg/day without changes in their food selection practices (see Table 4 of 58 FR 53254 at 53292). While the agency must ensure that the use of folic acid in the food supply is safe, it must also provide as great an opportunity as is prudent and rational for all women of childbearing age to increase their intake to the recommended level. The agency concludes that a level of 140 µg/100 g is the most appropriate fortification level for enriched cereal-grain products because, based on the results of its estimated daily intakes, fortification at this level will provide daily intakes for the nontarget population that remain within the recommended safe upper limit of 1 mg/day, while providing increased intakes of folate for women in their childbearing years (see Table 7 of 58 FR 53254 at 53295).

The agency notes, however, that it has reconsidered its proposed fortification level for breakfast cereals. As fully discussed in the food additives final rule, published elsewhere in this issue of the Federal Register, FDA is permitting breakfast cereals to contain up to 400 µg of folic acid per serving. As explained in that document, the estimates for total daily folate intake that FDA presented in the folic acid health claims proposal were based on the assumption that all breakfast cereals were fortified at 400 µg/serving. Based on those estimates, daily folate intake for certain groups in the nontarget population could exceed the recommended safe upper limit of 1 mg/day. Currently, however, only about 3 to 6 percent of breakfast cereals fortify at 400 µg/serving. The agency has found no reason to expect that this percentage will change and, therefore, considers it unlikely that daily folate intake in the nontarget population will exceed 1 mg with the fortification program adopted in this final rule and in the food additives final rule.

#### *D. Optional Versus Mandatory*

Because of the increased health risk to persons with vitamin B<sub>12</sub> deficiency caused by increased levels of folate intake, FDA solicited comments in the standards of identity proposal on whether the addition of folic acid to enriched cereal-grain products should be required as proposed or made optional.

12. A few comments fully supported the agency's proposal to require folic acid addition to the enriched cereal-grain products. These comments contended that required addition of folic acid was an appropriate means of increasing the daily folate intake of women in the target population.

However, the majority of the comments that responded to this issue stated that fortification should be voluntary. The comments cited varied reasons in support of their position. Some comments stated that the addition of folic acid to enriched cereal-grain products should be optional pending further evidence that the benefits outweigh the risk of masking vitamin B<sub>12</sub> deficiency. These comments contended that mandatory fortification of a wide variety of common products may create difficulty for people wishing to avoid folic acid. Furthermore, the comments asserted that FDA failed to establish why mandatory fortification would be necessary given that under current regulations voluntary fortification of standardized foods with folic acid is prohibited.

Other comments recommended optional fortification so that millers will not have to change their enrichment premixes for the general flour supply, thereby minimizing the costs associated with fortification, i.e., label changes, analytical testing, and inventory and supply coordination, especially for products exported to countries that do not permit folic acid fortification. The comments also stated that voluntary fortification would facilitate compliance with the various State enrichment laws.

A few comments opposed to mandatory fortification stated that FDA failed to offer information as to why voluntary fortification would not be sufficient to accomplish the public health goal of decreasing the incidence of pregnancies with neural tube birth defects. The comments urged FDA to establish a voluntary fortification program for enriched cereal-grain products and to reassess the need for a mandatory fortification in several years. One of these comments acknowledged, however, that it is difficult to predict the extent of voluntary fortification.

A small number of comments supported voluntary fortification for only the enriched noodle and macaroni products. The comments contended that voluntary compliance is consistent with FDA's current standards of identity for enriched noodle and macaroni products with regard to vitamin D, calcium, and wheat germ.

The agency does not agree with the comments that argued that the fortification of enriched cereal-grain products should be voluntary. In accepting the PHS' and Folic Acid Subcommittee's recommendation to include fortification as part of an overall plan to increase the folate nutriture of women of childbearing age, FDA has concluded that in order for a fortification program to be effective,



fortification must be mandatory for the enriched cereal-grain products. FDA is concerned that if it made fortification voluntary, and voluntary fortification were not widespread, there would be only a negligible increase in the daily folate intake of the target group, and the intent of this rulemaking would have been defeated. FDA finds that there is a public health need for women in their childbearing years to have adequate folate intake, and that the only way that it can ensure that they will have such an intake is through mandatory fortification.

FDA has traditionally used mandatory fortification to restore nutrients lost during the processing of cereal grains and thereby to address the need for reducing the risk of certain vitamin deficiency-related problems. The comments have not persuaded the agency that the same basic approach should not be applied in this case, where low folate intake represents a risk factor for a neural tube defect-affected pregnancy. USDA consumption data show that 90 percent of women of childbearing age consume cereal-grain products. Thus, mandatory fortification of cereal grains will, as stated above, increase folate intake among the target group, without requiring significant change in dietary patterns. Consequently, mandatory fortification of enriched cereal grains will help to ensure that the daily intake among the target group will reach the PHS recommended level of 400 µg. Voluntary fortification does not offer the same likelihood that folate intake will result in intakes that approach the PHS recommendation because the decision to fortify with folic acid will be at the discretion of individual manufacturers. Therefore, voluntary fortification will not adequately address the need for increased folate intake among women of childbearing age.

FDA derived the fortification levels established in this final rule based in part on a safe upper limit of 1 mg folate/day. The agency has concluded that mandatory fortification of the enriched cereal-grain products at the levels provided in this final rule is not likely to increase the risk of "masking" anemia in vitamin B<sub>12</sub> deficient persons. Thus, the fortification program that FDA is adopting will help to ensure that the amount of folate that people in all groups of the population can reasonably be expected to consume will not exceed 1 mg/day. As discussed in the food additives final rule, the agency has examined the available data on the levels of folate that may mask anemia of vitamin B<sub>12</sub> deficiency and concluded

that a daily intake of up to 1 mg of folate is safe.

In response to concerns raised by millers regarding label changes, analytical testing, and inventory and supply coordination, FDA recognizes that manufacturers will need ample time to implement the changes required by this amendment of the standards of identity. As discussed below in the effective date section, FDA is permitting manufacturers time to coordinate any necessary changes that need to be made throughout the chain of food production to comply with the requirements established in this final rule as well as with the requirements set out in part 101 (21 CFR part 101).

The agency notes that manufacturers will continue to have the option of using unenriched cereal-grain products as ingredients in foods and to add enrichment nutrients to those products as they choose. Several comments from industry representatives raised a concern that the provisions in the food additive proposal would not permit addition of folic acid at the bakery site. To the contrary, as discussed in the food additives final rule, FDA will permit addition of folic acid at the bakery site as long as it is in compliance with the governing standard of identity. Consequently, manufacturers will have the same option of adding folic acid as they have with other enrichment nutrients when preparing foods that are made with unenriched cereal-grain ingredients. The agency notes, however, that any products marketed as a standardized enriched cereal-grain product will have to contain folic acid at the levels established in this final rule, and that these requirements preempt state enrichment requirements that are not identical (see section 403(a) of the act (21 U.S.C. 343(a))).

With regard to exported products, the agency recognizes that manufacturers may be required to maintain separate inventories for foreign and domestic sales. While FDA recognizes the importance of reducing trade barriers, its first obligation is to protect and promote the health of U.S. consumers. In that regard, the agency concludes that, because the fortification program adopted in this final rule is necessary to significantly reduce the incidence of neural tube defect affected pregnancies, it would not constitute an illegal trade barrier.

#### *E. Other Issues*

13. One comment from a consumer interest group recommended that if research and monitoring does not establish in the next 2 years that the risk of increasing folate intakes is significant

for persons affected with vitamin B<sub>12</sub> deficiency or any folate-related diseases, then FDA should increase the fortification levels in grain products or other foods and require that upper safe limits be disclosed in higher dose products. This comment urged FDA to initiate a rulemaking to restore refined grain products with most of the vitamins and minerals that are removed during milling as recommended by the Food and Nutrition Board in 1974. The comment stated its belief that such an approach would raise few safety concerns and would not be costly because manufacturers are already equipped to add nutrients to food.

FDA cannot at this time commit to increasing the levels of folic acid that may be added to food within the next several years. However, as stated above, should data become available that demonstrate that modifications need to be made to improve the effectiveness of the intervention program, and evidence be developed that the safe upper limit can be raised, FDA will decide what action is necessary. The agency notes, however, that the action it is taking in this rulemaking will more than compensate for the amount of folate lost during the milling process.

As for the comment's request that FDA initiate rulemaking to restore to refined grain products other vitamins and minerals that are removed during milling raises, the agency notes that the request issues outside the scope of this rulemaking. Therefore, no action on this request is appropriate at this time.

14. Several comments raised concern regarding the impact of the proposed regulation on foreign trade. One comment from a foreign trade association urged FDA to delay finalizing the proposed regulation to provide the International Harmonization Working Groups the opportunity to review the proposal and recommend a strategy that would serve public health goals, while achieving the spirit and intent of the North American Free Trade Agreement (NAFTA). Another comment stated that the extra costs and inherent inefficiencies of separate production runs could preclude some manufacturers from the export marketplace.

Other comments stated that the lack of consistent requirements for folic acid fortification between major trading partners, e.g., the United States and Canada, would create problems in cross-border trade and could result in higher costs for both U.S. and foreign consumers. Furthermore, these comments asserted that inconsistent requirements could reduce the competitiveness of domestic

manufacturers who export their products. Thus, the comments urged FDA to resolve the issue of exporting folic acid enriched products to foreign countries by working with foreign governments to permit export of folic acid-enriched food.

FDA recognizes that the provisions it is adopting in this final rule may be inconsistent with the fortification policies of other countries. However, as discussed above, the agency finds that the action that it is taking in this final rule is necessary to adequately protect the public health of U.S. consumers. FDA will continue to work with officials in other countries, particularly parties to NAFTA, to find ways to reduce barriers to cross-border trading of cereal-grain products and other foods.

#### F. Specific Standards of Identity

In this document, the agency is providing for the addition of folic acid at the level of 140 µg/100 g to the individual enriched cereal-grain products that are the subject of standards of identity. The agency described in depth the method that it used in arriving at the levels of addition for folic acid in the specific standards of identity in the standards of identity proposal. FDA will not describe that method again in this document except to the extent that clarification is warranted in response to specific comments. For a complete discussion of the basis on which FDA established the enrichment levels for the subject standards of identity, the agency refers interested persons to the standards of identity proposal (58 FR 53305 at 53307 to 53309).

##### 1. Bakery and Wheat Flour Products

15. One comment, while supportive of the proposal to fortify cereal-grain products, suggested that a range of levels be permitted for addition of folic acid to all enriched cereal-grain products because of the inherent variation in the addition of the vitamins, the distribution of the vitamins in a food, and the analytical methodology. The comment suggested that FDA permit the addition of folic acid within a range of 24 to 35 percent over the amount established for each individual standard. For example, the comment suggested that the proposed amount of 0.7 mg/lb for enriched flour should be revised to 0.7 to 0.91 mg/lb. The comment argued that this scheme is the same as that used for enrichment in the macaroni and noodle standards and is needed for the same reasons that it is provided for in those standards.

FDA does not agree that it is necessary to provide for a range in the

level of folic acid used in the production of all enriched cereal-grain products. Providing for a single level, with provision for reasonable overages within the limits of current good manufacturing practice (CGMP), has worked well with the other nutrients (thiamin, niacin, riboflavin, and iron) required to be added to enrich bread, rolls, and buns and various flour products. The provision for "reasonable overages" in the standards for enriched bread, rolls, and buns (§ 136.115(a)(3)) and enriched flour (§ 137.165(c)) provides manufacturers with flexibility to ensure that required levels for the added nutrients will be met, and that these levels will be maintained throughout the shelf life of the food under customary conditions of distribution and storage. While FDA is not establishing a specific upper limit for folic acid addition, the agency advises that reasonable variations for overages of folic acid will be assessed on the same basis as that for the other added nutrients in these foods. Those reasonable variations are based on a number of factors, including the technology of nutrient addition, the possibility of nutrient deterioration, the firms' quality control procedures, and appreciation by the manufacturer of these factors.

FDA acknowledges that some of the standards for enriched cereal-grain products that are the subject of this final rule specify the levels of added nutrient (thiamin, riboflavin, and iron) in terms of ranges, and FDA has continued this approach with respect to the addition of folic acid in those products. In addition, the agency notes that it received a petition (Docket No. 94P-0413/CP 1) subsequent to the issuance of the folic acid health claims proposal to amend the standards for enriched macaroni and noodle products to provide for nutrient addition in terms of a single level with provision for reasonable overages. However, FDA is not making the change to a single enrichment level in those standards at this time because, while it has reached a final decision on folic acid fortification, it has not had an opportunity to fully analyze the petition. FDA is not aware of any reason why it should delay action in the present rulemaking while it analyzes the petition. Thus, until such time as the agency rules on the petition, the standards in question will continue to provide for nutrient addition in terms of ranges.

The ranges established in those standards provide a measure of flexibility in selecting the target level when nutrients are added to foods that consist of large particles such as farina

or rice, or for preparations (e.g., semolina or other ingredients) used for manufacturing enriched macaroni or noodle products. The nutrients, which usually are in the form of a fine powder, have a tendency to settle out and to make uniform blends with the cereal grains more difficult to achieve. In such instances, manufacturers, depending on their application process, may select target levels at the upper end of the range to ensure that the minimum levels established for the nutrients will be met. Thus, to enable manufacturers to adhere to procedures that will deliver the minimum level of nutrients required by the standards and to compensate for variables in the processing operations, the agency is continuing to provide for nutrient additions in terms of ranges for the other enriched foods as set forth below.

FDA also notes that the regulations for nutrition labeling in § 101.9(g)(4)(i) require that added nutrients be present in the food at levels that are at least equal to the amount declared on the label. In addition, § 101.9(g)(6) provides for reasonable overages within the limits of CGMP. Thus, the manufacturer bears the responsibility of ensuring that not only will the requirements for added nutrients in the respective standards of identity be met, but also that the content of any added nutrient is accurately declared in nutrition labeling. Therefore, consumers should receive the stated quantity of each added nutrient whether the standard provides for the added nutrient in terms of a single level or a range.

a. *Enriched flour.* No specific comments were received on the fortification of enriched flour with folic acid. Thus, as proposed, FDA is requiring that enriched flour contain 0.7 mg/lb of folic acid. FDA derived this value by adding the fortification level of 0.635 mg/lb to the Food and Nutrition Board's folate value of unfortified flour of 0.076 mg/lb, which yields 0.711 mg/lb. The agency rounded this value to 0.7 mg/lb. Accordingly, based on this calculation, FDA is amending the standards of identity for enriched flour (§ 137.165) and enriched self-rising flour (§ 137.185), and, by cross-reference, enriched bromated flour (§ 137.160), to require that these foods contain 0.7 mg/lb of folic acid.

b. *Enriched bread, rolls, and buns.* FDA is amending the standards of identity for enriched bread, rolls, and buns in § 136.115 to require that these foods contain 0.43 mg/lb of folic acid. This rate of fortification is proportionally consistent with the fortification rate for the B vitamins (thiamin, riboflavin, and niacin) when

enriched flour is used in making these foods. For example, the levels of thiamin, riboflavin, and niacin in enriched flour (§ 137.165) are 2.9, 1.8, and 24.0 mg/lb, respectively, and in enriched bread (§ 136.115) are 1.8, 1.1, and 15.0 mg/lb, resulting in a ratio of approximately 1.62 to 1. In the case of the level of folic acid, the level for enriched flour is 0.7 mg/lb compared to 0.43 mg/lb for bread, resulting in a ratio 1.63 to 1. The levels of enrichment specified for the B vitamins and folic acid content are slightly lower in enriched bread products than in enriched flour to allow the bread products to be made from the standardized enriched flour without further fortification.

c. *Enriched farina*. In the standards of identity proposal, FDA proposed to establish a fortification level for folic acid in enriched farina (§ 137.305) on the same basis as that for enriched wheat flour, i.e., 1 lb of the food would contain not less than 0.7 mg of folic acid.

One comment disagreed with the agency's rationale and argued that enriched farina is a different product than enriched wheat flour and therefore should not be fortified at the same level as enriched wheat flour. The comment asserted that farina is used differently than flour. For example, according to the comment, farina is often used as an ingredient in the less expensive pastas to replace the more expensive semolina. The comment pointed out that farina is also eaten as a hot cereal, and that precooked breakfast cereals are fortified with folic acid. The comment did not offer an alternative fortification level or data on which an alternative level could be based.

Because both wheat flour and farina are made from the endosperm of wheat, that portion of the wheat kernel that remains after the bran layer and germ have been removed, and because it is the bran layer and germ that contain most of the B vitamins, including the naturally occurring folate, the amount of B vitamins lost during processing would be similar in both foods. Therefore, the agency finds that it is reasonable to fortify both flour and farina on the same basic level of 140 µg/100 g.

However, FDA acknowledges that enriched farina and enriched flour may serve different functions. Farina is often used as a substitute for a flour-containing food, e.g., as a hot cereal at breakfast, with or without other cereal-grain products being consumed at that meal, and it may be used in other foods such as pasta. However, the agency finds no basis to change the fortification level based on these possible end uses

of the products because these uses are governed by other regulations. For example, when farina is used as an ingredient in the manufacture of precooked or instant breakfast cereal products, the level of enrichment is governed by the food additive regulation in § 172.345. That regulation provides that such ready-to-eat cereals may be enriched with folic acid up to 100 percent of the daily value per serving (i.e., 400 µg/serving). Neither this final rule nor the food additive final rule published elsewhere in this issue of the Federal Register, would affect the continued addition of folic acid to the precooked or ready-to-eat breakfast cereals that are manufactured with farina.

With respect to pasta products, the agency notes that the standard of identity for enriched macaroni and noodle products provides for the use of farina as an ingredient. However, the agency is not persuaded that it should adjust the fortification level for farina based on this possible use of this food. In cases where farina is used as an ingredient in an enriched macaroni or noodle product, the manufacturer has the option of adding enrichment nutrients to the farina at the flour mill or at the manufacturing facility to meet the requirements of the standard of identity for enriched macaroni or noodle products.

One comment pointed out that farina is not washed before cooking as had been noted in the proposal, and, thus, washing should not be a factor in determining appropriate fortification levels.

The agency acknowledges that current farina product labels do not suggest that enriched farina products need to be rinsed before cooking. Thus, with current technology, rinsing of the enriched farina product would not be a factor in deciding on an appropriate value for vitamin and mineral addition to farina. However, the agency notes that the proposed upper limit was not based solely on the fact that the product may be rinsed but also on the fact that it may be diluted when prepared in other recipes. The comment did not offer data to persuade the agency to deviate from the proposed upper limit of folic acid addition. Thus, as proposed, the agency is amending the standard of identity for enriched farina to provide for an upper limit for folic acid addition (0.87 mg/lb) that is approximately 25 percent higher than the minimum of 0.7 mg/lb as it has done for the other B vitamins (thiamin, riboflavin, and niacin) that are required to be present in enriched farina.

## 2. Corn and Rice Products

a. *Enriched corn grits*. No specific comments were received regarding the addition of folic acid to enriched corn grits. Thus, as proposed, FDA is amending § 137.235 to require fortification of enriched corn grits with the same level of folic acid as that established for enriched wheat flour products, such that each pound of the food would contain at least 0.7 mg of folic acid. FDA is also establishing the proposed upper limit for folic acid fortification of 1.0 mg/lb, which is approximately 50 percent higher than the minimum of 0.7 mg/lb, as it has done for the other B vitamins (thiamin, riboflavin, and niacin) that are required to be present in enriched corn grits.

The agency notes that it published a proposed rule in the Federal Register of October 13, 1995 (60 FR 53480), that would revoke the standard of identity for enriched corn grits. If comments to the proposal support revocation of this standard of identity, the provisions set forth in this final rule for enriched corn grits will also be revoked. FDA believes, however, that enriched corn grits is a widely consumed food that is likely to be eaten by women in need of additional sources of folate. Therefore, should FDA revoke this standard of identity, the agency is prepared to amend § 172.345, the food additive regulation on folic acid, to include fortified grits to the list of nonstandardized foods to which folic acid may be added.

b. *Enriched corn meals*. No specific comments were received regarding the enrichment of corn meal products with folic acid. Thus, as proposed, FDA is amending the standard of identity in § 137.260 to provide for a minimum folic acid level that is consistent with that established for enriched flour, such that each pound of the food contains 0.7 mg. Because corn meal products may be used as substitutes for wheat flour products, the agency believes, as discussed in the standards of identity proposal (58 FR 53305 at 53308), that consumers expect to be able to obtain the same levels of nutrients from enriched corn meals as from enriched wheat flour. FDA is also establishing an upper limit for folic acid addition (i.e., 1.0 mg/lb which is approximately 50 percent higher than the minimum fortification level), as has been done for the added B vitamins. The upper limit on the other B vitamins is intended to prohibit addition of excessive amounts of the nutrient and to ensure uniformity in composition of corn meals. FDA finds that, for the same reasons, an upper

limit on the addition of folic acid of 1.0 mg/lb is necessary.

c. *Enriched rice.* The folic acid content of rice varies from 0.008 mg/100 g (0.036 mg/lb) for white rice to 0.020 mg/100 g (0.090 mg/lb) for brown rice (Ref. 7). FDA proposed to amend the standard of identity for enriched rice to provide for the addition of not less than 0.7 mg and not more than 1.4 mg of folic acid per pound (58 FR 53305 at 53312). The agency also noted in the standards of identity proposal that rice in the United States may be enriched by addition of a powder mixture containing the added nutrients or by use of a rice premix consisting of rice kernels coated with a concentrated nutrient mix. When the powder enrichment procedure is used, the label of the package generally bears a statement that the rice should not be rinsed before or drained after cooking, in accordance with § 137.350(c), to ensure that the rice retains the added nutrients. However, the agency stated, there is no assurance that these instructions are being followed. In the case of the rice premix, a special coating is applied to the rice kernels, so that the added nutrients will not be washed off if the product is rinsed before cooking. Rice coated with the premix is blended with unenriched rice such that the finished enriched rice product will contain the required minimum levels of added nutrients. The agency stated that the proposed range would provide flexibility in the production of the enriched rice and ensure that the food, when prepared for consumption, will contain the required minimum levels of nutrients.

16. According to comments on the standards of identity proposal, most enriched rice produced in this country is manufactured using the powder procedure to add nutrients. A comment stated that some rice processors are very concerned about the addition of an enrichment powder mix containing folic acid because folic acid could result in off colors, taste, and aromas in the enriched rice. The comment maintained that firms fear that consumers may reject the enriched rice product if it does not possess the usual white color. It further stated that processors needed additional time to conduct research on the addition of folic acid to rice.

While FDA acknowledges that the provision in the enriched rice standard for the addition of riboflavin has been stayed because of objections from the industry stating that riboflavin addition results in a yellow discoloration being imparted to the rice that is unacceptable to consumers (23 FR 1170, February 25, 1958), the agency has not received any information from rice processors that

demonstrates that addition of folic acid to rice will result in off colors, taste, or aromas in the enriched rice product. Thus, as proposed, the agency is amending the standard of identity for enriched rice (§ 137.350) to include a range for the folic acid fortification level, 0.7 mg/lb to 1.4 mg/lb, with the lower limit being consistent with the folic acid fortification level for enriched wheat flour. FDA concludes that use of the same minimum level of fortification is appropriate because it is consistent with the Food and Nutrition Board's recommendation that the same restoration level be used for wheat flour, corn products, and rice (although the Food and Nutrition Board only recommended addition at restoration levels). FDA is also establishing an upper limit for folic acid fortification of enriched rice of 1.4 mg/lb, as it has done with other enrichment nutrients added to rice. As discussed in the standards of identity proposal (58 FR 53305 at 53309), the upper level is based on the way that rice is fortified in this country.

The agency recognizes that manufacturers will need time to experiment with the addition of folic acid to their products. FDA is providing approximately 2 years from the publication date of this final rule to allow manufacturers to test their ability to comply with the new requirements and to make appropriate label changes.

17. One comment stated that, because the powder-enriched rice suffers substantial nutrient loss when it is washed (as rice is by many consumers), it is unlikely that folate intakes will increase as much as FDA estimates. The comment suggested that the agency should, consequently, increase the fortification level.

FDA disagrees with the comment. For those consumers who wish to consume "enriched" rice, the agency has provided requirements in the standard of identity for enriched rice to ensure delivery of the required nutrients. Section 137.350(c) requires that enrichment nutrients be present in the rice in such form and at such levels that if the enriched rice is washed, it contains not less than 85 percent of the minimum quantities of the nutrients required to be present in the enriched rice. If they are not present in such form or at such levels to comply with these minimum requirements, the label of the enriched rice must bear the statement "to retain vitamins do not rinse before or drain after cooking" immediately following the name of the food. In addition, the label cannot bear cooking directions that call for washing or draining the enriched rice. In the case of precooked enriched rice, the package

must be labeled with directions for preparation that, if followed, will avoid washing away or draining off enrichment ingredients.

As discussed above, FDA is providing for addition of folic acid at the level of 140 µg/100 g of the enriched cereal-grain products. The agency has concluded that this fortification level is necessary to help ensure that the total consumption level will not exceed the recommended daily consumption level of 1 mg (or 1,000 µg). To minimize the potential losses in enrichment nutrients in rice, the agency had provided for a range in the levels, with an upper limit that is twice that of the minimum level required to be present in the rice. Thus, rice processors who use the powder-enrichment procedure, where nutrient losses would be expected to be greater, will be able to use a level of enrichment nutrients that makes it likely that consumers will receive the minimum levels of nutrients required to be in the food.

### 3. Macaroni and Noodle Products

The standards of identity for enriched macaroni products (§ 139.115), enriched nonfat milk macaroni products (§ 139.122), and enriched noodle products (§ 139.155), and the cross-referenced standards of identity for enriched vegetable macaroni products (§ 139.135) and enriched vegetable noodle products (§ 139.165), provide for significantly higher levels of nutrient addition than the related flour standards of identity because these products are usually cooked in a large amount of water that is usually discarded after cooking and before consumption of the macaroni and noodle products.

18. One comment asserted that because of the preparation process for macaroni and noodle products, vitamin retention data are absolutely essential before any level of enrichment can be discussed. Thus, the comment recommended that FDA delay implementation of folic acid fortification of cereal-grain products until more concrete information is available on vitamin retention with cooking.

FDA is not delaying the implementation of folic acid fortification, as suggested by the comment, because of the need to increase the folic acid levels in the diets of women of childbearing age. The agency recognizes that there will be losses in the content of water soluble vitamins when the enriched macaroni and enriched noodle products are cooked in water, and that water is drained from the foods before consumption (Ref. 8). The agency also

acknowledges that data on retention of the vitamins (thiamin, niacin, and riboflavin) required to be added to enrich these foods are limited, and that it is difficult to make inferences as to the retention of added folic acid when folic acid enriched products are cooked in water, and the water is discarded. However, there are some data to suggest that the retention rates are similar.

According to a study conducted by Ranhortra, et al. (Ref. 8), on the retention rates of the thiamin, niacin, and riboflavin in three enriched pasta products (spaghetti, noodles, and macaroni), at least 50 percent (75 to 77 percent on average) of the added nutrients was retained after cooking in water and draining. This study looked at the retention of the naturally occurring folate in the pasta products, before and after cooking, and found that the retention rate was 77 to 79 percent. Based on this data, FDA does not expect that the retention rate of folic acid in these products would be significantly different from the retention rates of the other B vitamins.

FDA recognizes that, as with other grain products, manufacturers will need to conduct research on the most effective means of adding folic acid and of ensuring that the added folic acid will be available in the finished food. Such studies will need to focus on not only the method of adding the nutrient but also on the stability of the vitamin during usual conditions of distribution and storage. The agency notes that similar studies were required when FDA established requirements for the addition of the other B vitamins to enriched cereal-grain products. In addition to studies, it may be necessary for manufacturers to develop label instructions on how the product should be prepared, e.g., instructions on limiting the amount of water to be used in its preparation or cooking time, and on whether the cooked food can be rinsed without loss of nutrients before serving, to ensure maximum retention of folic acid and the added water soluble nutrients.

FDA is requiring the addition of folic acid to macaroni and noodle products in the same proportion as it is requiring such addition to enriched flour, except that the required level (expressed in terms of a range) will be approximately 25 percent higher for macaroni and noodle products than the required level of folic acid that is to be added to flour. This 25-percent increment is consistent with the requirements for the other added nutrients (thiamin, riboflavin, niacin, and iron) in the enriched macaroni and noodle products

standards, compared to those in the standards of identity for flour products.

Accordingly, as proposed, FDA is requiring that the enriched macaroni and noodle products contain from 0.9 to 1.2 mg/lb of folic acid.

#### *G. Effective Date*

19. Many comments expressed concern over the statement in the standards of identity proposal that the final rule would become effective 1 year after publication. The comments stated that it would be difficult and impractical to synchronize the addition to a food of a folic acid-fortified enriched cereal-grain product with the availability of revised labels for that food that declare folic acid in the ingredient statement. These comments pointed out that enrichment nutrients are generally not added to each separately labeled product but are added to thousands of pounds of flour at the flour mill, the flour is sold to other manufacturers as an ingredient, and then this ingredient is used in many different products. Thus, the comments asserted that as a matter of economic necessity, the enrichment of all these products occurs at the same time, regardless of the availability of new labeling. One comment recommended that FDA establish an effective date of at least 2 years from the date of publication of the final rule. The comment asserted that a 2-year period would allow adequate time to incorporate changes on labels of slower moving products as well as products with higher retail turn rates. Thus, the comment continued, existing packaging inventory could be used, thereby reducing the cost impact of the regulation. Another comment suggested a "phase-in" period of at least 3 years or, in the alternative, an effective date consistent with the next uniform effective date, whichever is later. In support of the suggestion, the comment asserted that a "phase-in" period would allow label changes to take place concurrent with the folic acid addition on a product-by-product basis. In addition, the comment contended, such action would allow manufacturers to exhaust their current label inventory and reduce the economic impact of the regulation. Moreover, the comment continued, additional time is needed for analytical testing for declaration of folic acid in nutrition labeling.

FDA acknowledges the concerns raised in these comments regarding label changes that must accompany the addition of folic acid to enriched cereal-grain products and to foods in which these products are used as ingredients. FDA is persuaded by the concerns

raised in the comments to establish an effective date that will provide manufacturers with time to implement the label and formulation changes required by the amendments established in this final rule. The agency agrees with the comment that suggested that FDA establish an effective date of at least 2 years from the date of publication of the final rule. A 2-year period would allow manufacturers time to exhaust current packaging inventory, add folic acid to their statement of ingredients and the nutrition facts panel as other changes are made to update package labeling, and subsequently ensure that packaging is available that accurately reflects the addition of folic acid to their products. Furthermore, the agency points out that a 2-year period is consistent with the amount of time given for implementation of the Nutrition Labeling and Education Act (NLEA) requirements. Thus, the effective date of this final rule will be January 1, 1998. The agency notes, however, that compliance with the requirements established in this final rule may begin immediately, provided that the label accurately reflects that folic acid has been added to the product. Furthermore, the agency will not object to the use of stickers to bring a product label into compliance with the ingredient labeling and nutrition labeling provisions. The agency notes, however, that unless the standardized food bears a claim about folate, the declaration of folate in the nutrition label is voluntary.

20. A few comments that raised concern about label changes that must accompany the addition of folic acid suggested that the agency permit folic acid to be added to the product without requiring declaration in the ingredient statement. One comment contended that there was no safety issue regarding folic acid that would require its declaration on the label.

Traditionally, the agency has not permitted manufacturers who change their formulas by adding or deleting ingredients to use noncompliant labels. Furthermore, as discussed in response to the previous comment, the agency is establishing an effective date in this final rule that will provide industry ample time to ensure that products enriched with folic acid are labeled in compliance with the regulations.

In response to the argument that the addition of folic acid need not be declared because it does not raise a safety issue, the agency advises that the act requires that all foods fabricated from two or more ingredients declare each of its ingredients by common or usual name in a list of ingredients. This

requirement applies without regard to whether there is a safety issue regarding the food. Consequently, the agency has not been persuaded by the comments to permit the addition of folic acid to foods without also requiring that folic acid be declared in ingredient labeling.

### III. Economic Impact

FDA has examined the impacts of this final rule to require the addition of folic acid to enriched cereal-grain products that conform to a standard of identity as required by Executive Order 12866 and the Regulatory Flexibility Act. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Regulatory Flexibility Act (Pub. L. 96-654) requires the analysis of options for regulatory relief for small businesses. FDA finds that this final rule is not a significant regulatory action as defined by Executive Order 12866. In compliance with the Regulatory Flexibility Act, the agency certifies that this final rule will not have a significant impact on a substantial number of small businesses.

On October 14, 1993 (58 FR 53305 at 53309), FDA published an economic impact analysis of the proposed requirements under the previous Executive Order (E.O. 12291). In the analysis, the agency evaluated the following regulatory options:

1. Improve dietary practices among women of childbearing age.
2. Require fortification with folic acid at 140 µg/100 g.
3. Require fortification with folic acid at: (a) A lower level, specifically 70 µg/100 g; or (b) a higher level, specifically 350 µg/100 g.

In response to the standards of identity proposal, the agency received several comments that provided information that has altered its economic impact analysis. Costs and benefits for each of the regulatory options are examined below.

#### A. Costs

Cost estimates are revised first for fortification at 140 µg/100 g followed by the cost estimates for fortification at 70 µg/100 g and 350 µg/100 g.

1. Require Fortification With Folic Acid at 140 µg/100 g

Costs of fortifying with folic acid at 140 µg/100 g include health costs and reformulation costs.

a. *Health costs.* Potential health costs of this regulatory option include the costs of neurologic disease associated with masking of the anemia of vitamin B<sub>12</sub> deficiency. Several studies have found that folic acid can mask the anemia of vitamin B<sub>12</sub> deficiency at levels as low as 250 µg/day. Although there is no scientific consensus on the percentage of diagnoses of vitamin B<sub>12</sub> deficiency anemia that would be complicated by folate intake at this level, the agency has determined that adverse health effects are not significant until folate intake reaches 1 mg/day. In the proposal, FDA tentatively concluded that the 140 µg/100 g level for fortification of enriched cereal grain products was the most appropriate level based on a regulation that would have required that fortification of all breakfast cereals be limited to 100 µg folic acid/serving. This limitation was proposed under a separate food additive regulation published elsewhere in the same Federal Register (58 FR 53312). With this option, 140 µg/100 g, FDA preliminarily concluded that intake of persons in the target and nontarget populations would remain below 1 mg/day.

Comments submitted in response to the proposal to limit breakfast cereals to 100 µg folic acid/serving persuaded the agency to allow breakfast cereals to continue to contain up to 400 µg folic acid/serving. If all breakfast cereals were fortified at the level of 400 µg/serving, some high end consumers could consume more than 1 mg folate/day. However, most cereals currently are fortified at a level of 100 µg/serving (25 percent of the reference daily intake (RDI)) and only an estimated 5 percent of breakfast cereals fortify at a level of 400 µg (100 percent of the RDI).

Further, it is unlikely that manufacturers of breakfast cereals will increase the folic acid level in cereals from 100 µg/serving to 400 µg/serving. Since most breakfast cereals that contain at least 40 µg/serving (10 percent of the RDI) of folic acid can now make health claims (if all other criteria are met), manufacturers have no incentive to reformulate from 100 µg to 400 µg per serving and incur reformulation costs.

There are a number of confounding uncertainties that make it difficult to estimate the potential health costs of folic acid fortification of enriched grain products (Ref. 9). These include:

1. Current intakes estimated from food consumption survey data may underestimate actual intakes due to underreporting of food intake;
2. The folate content of foods may be underestimated due to methodologic difficulties;

3. Good data on the distribution of dietary supplement intake are not available;

4. Estimates of masking of anemia (with subsequent progression of neurologic symptoms) based on enumerating only those associated with pernicious anemia would underestimate potential adverse effects because all vitamin B<sub>12</sub> deficiencies may lead to neurologic problems; and

5. It is difficult to predict effects of changes in dietary patterns that occur simultaneously with, but independently of, this regulation. Such changes may be the result of educational efforts by various organizations, physicians, and health care providers or in response to health claims.

The last factor is particularly problematic. Recent surveys have shown a growing awareness of the value of increased folate intake among both the population as a whole and, specifically, among women of childbearing age. From 1994 to 1995, awareness of the problems associated with insufficient folic acid intake grew from 28 to 44 percent among women of all ages (Ref. 10). As awareness grows, it is likely that folic acid intake will increase in the target group. In addition, new label claims allowed by the final rule for health claims on the association between folate intake and a reduced risk of NTD's are also expected to increase folic acid intake among women of childbearing age. However, the survey mentioned above also showed that such awareness is strongly positively correlated with education, so that these messages may not reach less well-educated women in the population.

In the folic acid health claims proposal, FDA tentatively found that there were several nontarget groups whose intake levels of folate may approach 1 mg/day (intakes > 800 µg/day) with a level of 140 µg/day and use of dietary supplements. These include individuals in groups including children 4 through 10 years of age and males 11 through 18, 19 through 50, and 51+ years of age. Individuals at risk of pernicious anemia include both males and females over 51 and Hispanic females ages 40 and above. The largest group at potential risk includes males over 51 who take dietary supplements. In order to be at risk of potential adverse effects from consuming greater than 1 mg folate/day individuals must: (1) Consume an excessive amount of folic acid through some combination of supplements containing folic acid and consumption of fortified enriched grain products and other products containing folic acid; and (2) have low vitamin B<sub>12</sub> status or have vitamin B<sub>12</sub> deficiency.

Because of the difficulties mentioned above, it is not possible to estimate the number of people in the high risk subgroup who fit all of these categories.

However, one such attempt has been made between the time of the standards of identity proposal and this final rule. In this analysis, Romano et. al. made the following assumptions:

1. The annual incidence of pernicious anemia is 9.5 to 16.7 per 100,000 persons (based on two European population-based studies);

2. With low level fortification, 5 to 10 percent of these patients would receive enough folic acid to mask the anemia of vitamin B<sub>12</sub> deficiency; and

3. Between "24 and 26 percent of patients with pernicious anemias whose anemias respond to folic acid develop neurologic signs" (Ref. 11).

Based on these assumptions, the authors estimated that approximately 500 people per year would develop neurologic disease as a result of low level folic acid fortification. Other authors contend that this estimate may considerably understate the number of cases (Ref. 12). On the other hand, one uncertainty not acknowledged by this analysis is that this rule may create a market for cereal-grain products that are not "enriched." A nonstandardized cereal-grain product could be produced that was not labeled as being enriched with folate (although it could have other vitamins and minerals added and be labeled to reflect this fact) and could be marketed to people at risk of vitamin B<sub>12</sub> deficiency. If such a market developed, and at-risk persons were encouraged to consume products not enriched with folic acid, this problem might be reduced. In addition, sale to high risk subgroups of nonstandardized products such as whole wheat breads (mentioned earlier in this preamble) which do not need to be enriched, may increase as a result of this rule.

Another uncertainty that would reduce the number of cases of masked anemia, mentioned by one comment, is the percentage of cases of B<sub>12</sub> deficiency that could be discovered with routine population screening. If such tests were performed proactively, B<sub>12</sub> deficiencies might be identified before neurologic symptoms developed.

In addition, it is not clear whether the European population-based studies that reported the annual incidence of diagnosed pernicious anemia are relevant to the U.S. population. Some population groups in the United States (e.g., African-American women) appear to experience an earlier age-at-onset of pernicious anemia than occurs with pernicious anemia in Northern

European countries, which are predominantly Caucasian populations.

Although not able to estimate an absolute number, FDA has calculated a cost per case of neurologic symptoms resulting from masking of the anemia of pernicious anemia so that a break-even point may be calculated at which point benefits would equal the costs. The cost-per-illness will be calculated using the sum of medical costs and the cost of lost utility. The majority of medical costs, which include costs for physicians, other hospital services, and drugs, are normally paid by insurance such that estimates based on willingness-to-pay to avoid death would not be likely to be included. Other utility losses, including death, pain and suffering, immobility, and lost productivity associated with morbidity, are calculated as a function of the willingness-to-pay (WTP) to avoid death. Thus, for example, each day of morbidity is a day spent in less than perfect health engendering some utility loss. That is, each day of illnesses is somewhere between a day of full utility, 1, and death, 0. Because WTP to avoid death does not include the medical expenditures mentioned above, these costs are calculated separately.

The expected utility loss estimates were calculated in the preliminary economic impact analysis (the PRIA) in the standards of identity proposal. The most common symptoms of a delay in the diagnosis of vitamin B<sub>12</sub> deficiency are permanent paresthesia (numbness or tingling) in the hands or feet and ataxia (inability to coordinate voluntary muscular movements).

In the standards of identity proposal, FDA estimated the cost per case to be approximately \$538,000 (Ref. 13). This estimate was calculated using weighted probabilities of a mild (95 percent) and a severe case (5 percent) and the value of expected utility loss per case of neurologic disability. For each state, mild and severe, a health status value was calculated that related the state to a day of "perfect health". Thus, a person with a mild case of neurologic disability is calculated to enjoy only 70 percent of the utility per day as that of a person in a perfectly healthy state. For a more severe case it would be approximately 50 percent (Ref. 14). Using the likely duration of each illness, the utility loss from a severe neurologic disability was found to be equivalent to a loss of 5.56 perfect-health years. From the value of a perfect health year, \$138,889 (Ref. 14), the value of expected utility loss per case of mild neurologic disability was estimated to be \$525,598. The utility loss due to severe neurologic disability was estimated in a similar fashion to be \$772,598 per case. The weighted value

(based on likelihood of a mild versus severe case) of a case of masked pernicious anemia leading to permanent adverse health effects was calculated as the weighted mean:  $(0.95 \times 525,598) + (0.05 \times 772,598) = \$537,948$ .

In addition to utility costs, hospital costs of neurologic effects due to pernicious anemia have been estimated by Romano et al. (Ref. 11). In this study, each neurologic case requires hospitalization once for an average duration of 16 days at \$867/day. After factoring in physician services and other direct and indirect costs, the total direct outlay cost of neurologic disease as a result of folic acid fortification was estimated to be \$33,000 per case (Ref. 11). Total costs per case are thus calculated to be \$570,000.

However, as mentioned in Romano et al., the cost estimate may be too high because these estimates assume that all neurologic disease would be severe, and mild cases may not require hospitalization (Ref. 11). In addition, this estimate may be too high if there were routine population wide screening for vitamin B<sub>12</sub> deficiency, although this is not currently occurring nor is it likely to be instituted. At the same time, however, the estimate may be too low if a case leads to later complications or to the need for lifelong skilled nursing care (Ref. 11).

These costs, lost utility and hospital costs, are not annual costs. Once someone has experienced permanent adverse health effects from masked pernicious anemia, that person ought not to be included in the costs estimated for subsequent years, since the discounted value of their permanent adverse health effects has already been calculated and attributed to the first year. Any costs in subsequent years would involve only those entering the at-risk age pool.

b. *Other health costs.* FDA is aware of the potential for other health problems resulting from increased long-term intakes of folic acid but has no data with which to quantify these costs.

c. *Reformulation costs.* Reformulation costs associated with this option were estimated in the proposal to be \$27 million for the first year. The cost of adding the required folic acid is approximately \$4 million per year. The cost of testing was estimated to be about \$2.5 million per year and the cost of the required label changes \$20 million. FDA will use these costs for this final rule as no comments were received on this part of the analysis.

In addition, some countries, such as Canada, do not allow folic acid fortification of these products. Thus, this option would require that separate



production runs be made for fortified products exported, to and imported from, these countries. This requirement may preclude some manufacturers from the export market. None of the comments provided information that would assist in determining the costs of having different international requirements.

## 2. Costs of Requiring Fortification With Folic Acid at Either 70 µg/100 g or 350 µg/100 g

The total cost of the option to fortify at 70 µg/100 g in the first year was estimated in the proposal to be \$25 million plus the cost of separate production runs for these products exported to and imported from certain foreign countries. For the option of fortifying with folic acid at 350 µg/100 g, the PRIA estimated a cost of \$1.88 billion annually.

With the latter option, the folate intake of some consumers at risk of vitamin B<sub>12</sub> deficiency (including pernicious anemia) would be raised to levels exceeding 1 mg per day. One comment to the proposal said that the estimated health costs of fortifying at this (higher) level were unrealistically high as FDA had failed to take into account that each subsequent year should only account for new cases (Ref. 11). Because of the problems with estimating numbers of people who will become ill at either level, FDA will not quantify these costs.

**Reformulation costs.** In the proposal, the cost of the folic acid required to fortify at 350 µg/100 g was estimated to be approximately \$10 million per year. The cost of testing was estimated to be \$2.5 million and the cost of the required label changes was estimated to be \$20 million.

## B. Benefits

### 1. Require Fortification with Folic Acid at 140 µg/100 g

The primary benefit of this option is a reduction in the number of infants born with NTD's each year. In addition, a possible benefit will be a reduction in cardiovascular diseases from intake of increased folate. However, there is still tremendous uncertainty with respect to the latter effect (for a more complete discussion, see folic acid food additive document published elsewhere in this Federal Register).

Based on a synthesis of information from several studies, including those which used multivitamins containing folic acid at a daily dose level of ≥ 0.4 mg, it was inferred that folic acid alone at levels of 0.4 mg per day will reduce the risk of NTD's. This conclusion was

based on two studies, one from a high risk population (Hungary) with a small number of subjects that was found to be 100 percent effective and another from a study that showed zero risk reduction in a low prevalence population (California and Illinois). From these studies, the PHS estimated a reduction of 50 percent of the number of NTD's in the United States. Other studies evaluated by PHS varied in their results. A possible explanation for the lack of effectiveness was that studies were conducted in populations with a low prevalence of NTD's which may not have had a folate-related subset of NTD's.

In a study by Shaw et al., the reduction in NTD risk associated with folate intake is consistent with other studies, but the reduced risk was found to be specific to particular subsets of the population, primarily non-Hispanic women and women whose education did not exceed high school (Ref. 15). For Hispanic women, the risk reduction was approximately 10 percent. In a study by Romano et. al., the 50 percent estimate of reduced risk of NTD's was used with literature-based sensitivity limits of 67 percent (Ref. 16) and 20 percent (Refs. 11 and 17).

In the proposal, FDA estimated that under the 140 µg/100 g option, 116 NTD's per year would be prevented (50 percent reduction). Initiation of this option was also estimated to prevent an additional 25 infant deaths each year. Total benefits of this option were estimated to be between \$651 and \$788 million per year.

There is no consensus on the dose-response relationship between folate intake and the reduction in risk of NTD's. However, using a lower bound of 10 percent and an upper bound of a 50 percent reduction in NTD's, the estimated reductions in total cases would be between 25 (5 deaths) and 125 (27 deaths) resulting in quantified benefits ranging from \$220 to \$700 million.

### 2. Require Fortification with Folic Acid at 70 µg/100 g and 350 µg/100 g

a. *70 µg/100 g.* The benefit of requiring fortification of these products at 70 µg/100 g was estimated in the proposal to be between \$326 and \$394 million. Using the sensitivity limits mentioned above, 10 to 50 percent of the estimated benefits would range from \$110 to \$346 million.

b. *350 µg/100 g.* The benefit of requiring fortification of these products at 350 µg/100 g is estimated to be between \$550 million and \$1.4 billion. This option is the only option that would generate significant health costs.

## C. Conclusion

In accordance with Executive Order 12866, the agency has analyzed the economic effects of this final rule and has determined that this rule, if issued, will not be an economically significant rule as defined by that order.

The cost of this final rule in the first year is estimated to be approximately \$27 million which includes the cost of relabeling, testing, and fortification. In addition, there may be some health costs associated with neurologic symptoms resulting from masking the anemia of vitamin B<sub>12</sub> deficiency as well as the cost of separate production runs for products exported to and imported from certain foreign countries. The cost of the proposed action in each year after the first year should be approximately 25 percent of the first year cost. The benefits are estimated to be between \$220 and \$700 million per year. Using a value of \$570,000 per case of masked pernicious anemia resulting in neurologic damage, the break-even number of these cases at which costs would equal benefits would fall between 386 and 1,228.

Although reformulation costs of this option are approximately \$27 million, the cost per firm is expected to be very small. Therefore, in accordance with the Regulatory Flexibility Act, FDA has determined that this rule will not have an adverse impact on a substantial number of small businesses.

## IV. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

## V. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Centers for Disease Control and Prevention, "Recommendations for the Use of Folic Acid to Reduce the Number of Cases of Spina Bifida and Other Neural Tube Defects," in *Morbidity and Mortality Weekly Reports*, 41, 1-7, 1992.
2. USDA, Nationwide Food Consumption Survey/Individual Intake-1987-1988, accession no. PB90-504044, National



Technical Information Service, Springfield, VA, 1990.

3. Food and Nutrition Board, National Research Council, National Academy of Sciences, Proposed Fortification Policy for Cereal-Grain Products, Washington, DC, 36 pp., 1974.

4. Nationwide Food Consumption Survey, Continuing Survey of Food Intakes by Individuals: Women 19–50 Years Old and Their Children 1–5 years, 1 day, 1985; United States Department of Agriculture, Hyattsville, MD: NFCS, CSFII, Report No. 85–1, 1985.

5. Subcommittee on Food Technology, Committee on Food Protection, Food and Nutrition Board, National Research Council, National Academy of Sciences, Proceedings of a Workshop on Technology of Fortification of Cereal-Grain Products, Washington, DC, May 16–17, 1977.

6. USDA Handbook 8–20: Composition of Foods, Cereal Grains, and Pasta, Raw Processed, Prepared. Rev., October 1989.

7. Hoffpauer, D.W., "Rice Enrichment for Today," *Cereal Foods World*, vol. 37, No. 10, pp. 757–759, 1992.

8. Ranhortra, G.S., J.A. Gelroth, F.A. Novak, and R.H. Matthews, "Retention of Selected B Vitamins in Cooked Pasta Products," *Cereal Chemistry*, vol. 60, No. 6, pp. 476–477, 1985.

9. Crane, N. et al., "Evaluating Food Fortification Options: General Principles Revisited with Folic Acid," *American Journal of Public Health*, vol. 85, No. 5, pp. 660–666, 1995.

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11. Romano, P.S. et al., "Folic Acid Fortification of Grain: An Economic Analysis," *American Journal of Public Health*, vol. 85, No. 5, pp. 667–676, 1995.

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14. Research Triangle Institute, "Quality of Well-Being Scale in Estimating the Value of Consumers' Loss from Food Violating the FD&C Act," vol. II, Final Report, 1988.

15. Shaw, G.M. et al., "Periconceptional Vitamin Use, Dietary Folate and the Occurrence of Neural Tube Defects," *Epidemiology Resources Inc.*, 1995.

16. MRC Vitamin Study Research Group, "Prevention of Neural Tube Birth Defects: Results of the Medical Research Council Vitamin Study," *Lancet*, vol. 338, pp. 131–137, 1991.

17. Mills, J.L., G.G. Rhoads, J.L. Simpson, G.C. Cunningham, M.R. Conley, M.R. Lassman, M.E. Walden, D.R. Depp, H.J. Hoffman, "The Absence of a Relation Between the Periconceptional Use of Vitamins and Neural-tube Defects," *New England Journal of Medicine*, 321:430–435, 1989.

## List of Subjects

### 21 CFR Part 136

Bakery products, Food grades and standards.

### 21 CFR Part 137

Cereals (food), Food grades and standards.

### 21 CFR Part 139

Food grades and standards.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR parts 136, 137, and 139 are amended as follows:

## PART 136—BAKERY PRODUCTS

1. The authority citation for 21 CFR part 136 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 379e).

2. Section 136.115 is amended by revising paragraph (a)(1) to read as follows:

### § 136.115 Enriched bread, rolls, and buns.

(a) \* \* \*

(1) Each such food contains in each pound 1.8 milligrams of thiamin, 1.1 milligrams of riboflavin, 15 milligrams of niacin, 0.43 milligrams of folic acid, and 12.5 milligrams of iron.

\* \* \* \* \*

## PART 137—CEREAL FLOURS AND RELATED PRODUCTS

3. The authority citation for 21 CFR part 137 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 379e).

4. Section 137.165 is amended by revising paragraph (a) to read as follows:

### § 137.165 Enriched flour.

\* \* \* \* \*

(a) It contains in each pound 2.9 milligrams of thiamin, 1.8 milligrams of riboflavin, 24 milligrams of niacin, 0.7 milligrams of folic acid, and 20 milligrams of iron.

\* \* \* \* \*

5. Section 137.185 is amended by revising paragraph (a) to read as follows:

### § 137.185 Enriched self-rising flour.

\* \* \* \* \*

(a) It contains in each pound 2.9 milligrams of thiamin, 1.8 milligrams of riboflavin, 24 milligrams of niacin, 0.7 milligrams of folic acid, and 20 milligrams of iron.

\* \* \* \* \*

6. Section 137.235 is amended by revising paragraph (a)(1) to read as follows:

### § 137.235 Enriched corn grits.

(a) \* \* \*

(1) It contains in each pound not less than 2.0 milligrams (mg) and not more than 3.0 mg of thiamin, not less than 1.2 mg and not more than 1.8 mg of riboflavin, not less than 16 mg and not more than 24 mg of niacin or niacinamide, not less than 0.7 mg and not more than 1.0 mg of folic acid, and not less than 13 mg and not more than 26 mg of iron (Fe);

\* \* \* \* \*

7. Section 137.260 is amended by revising paragraph (a)(1) to read as follows:

### § 137.260 Enriched corn meals.

(a) \* \* \*

(1) It contains in each pound not less than 2.0 milligrams (mg) and not more than 3.0 mg of thiamin, not less than 1.2 mg and not more than 1.8 mg of riboflavin, not less than 16 mg and not more than 24 mg of niacin or niacinamide, not less than 0.7 mg and not more than 1.0 mg of folic acid, and not less than 13 mg and not more than 26 mg of iron (Fe);

\* \* \* \* \*

8. Section 137.305 is amended by revising paragraph (a)(1) to read as follows:

### § 137.305 Enriched farina.

(a) \* \* \*

(1) It contains in each pound not less than 2.0 milligrams (mg) and not more than 2.5 mg of thiamin, not less than 1.2 mg and not more than 1.5 mg of riboflavin, not less than 16.0 mg and not more than 20.0 mg of niacin or niacinamide, not less than 0.7 mg and not more than 0.87 mg of folic acid, and not less than 13.0 mg of iron (Fe).

\* \* \* \* \*

9. Section 137.350 is amended by revising paragraph (a)(1) to read as follows:

### § 137.350 Enriched rice.

(a) \* \* \*

(1) Not less than 2.0 milligrams (mg) and not more than 4.0 mg of thiamin, not less than 1.2 mg and not more than 2.4 mg of riboflavin, not less than 16 mg and not more than 32 mg of niacin or niacinamide, not less than 0.7 mg and not more than 1.4 mg of folic acid, and not less than 13 mg and not more than 26 mg of iron (Fe).

\* \* \* \* \*

**PART 139—MACARONI AND NOODLE PRODUCTS**

10. The authority citation for 21 CFR part 139 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 379e).

11. Section 139.115 is amended by revising paragraph (a)(1) to read as follows:

**§ 139.115 Enriched macaroni products.**

(a) \* \* \*

(1) Each such food contains in each pound not less than 4.0 milligrams (mg) and not more than 5.0 mg of thiamin, not less than 1.7 mg and not more than 2.2 mg of riboflavin, not less than 27 mg and not more than 34 mg of niacin or niacinamide, not less than 0.9 mg and not more than 1.2 mg of folic acid, and not less than 13 mg and not more than 16.5 mg of iron (Fe);

\* \* \* \* \*

12. Section 139.122 is amended by revising the first sentence of paragraph (a)(3) to read as follows:

**§ 139.122 Enriched nonfat milk macaroni products.**

(a) \* \* \*

(3) Each such food contains in each pound not less than 4.0 milligrams (mg) and not more than 5.0 mg of thiamin, not less than 1.7 mg and not more than 2.2 mg of riboflavin, not less than 27 mg and not more than 34 mg of niacin or niacinamide, not less than 0.9 mg and not more than 1.2 mg of folic acid, and not less than 13 mg and not more than 16.5 mg of iron (Fe). \* \* \*

\* \* \* \* \*

13. Section 139.155 is amended by revising paragraph (a)(1) to read as follows:

**§ 139.155 Enriched noodle products.**

(a) \* \* \*

(1) Each such food contains in each pound not less than 4 milligrams (mg) and not more than 5 mg of thiamin, not less than 1.7 mg and not more than 2.2 mg of riboflavin, not less than 27 mg and not more than 34 mg of niacin or niacinamide, not less than 0.9 mg and not more than 1.2 mg of folic acid, and not less than 13 mg and not more than 16.5 mg of iron (Fe);

\* \* \* \* \*

Dated: February 26, 1996.

David A. Kessler,

*Commissioner of Food and Drugs.*

Donna E. Shalala,

*Secretary of Health and Human Services.*

[FR Doc. 96-5014 Filed 2-29-96; 12:03 pm]

BILLING CODE 4160-01-P

**21 CFR Part 172**

[Docket No. 91N-100F]

**Food Additives Permitted for Direct Addition to Food for Human Consumption; Folic Acid (Folacin)**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of folic acid in foods that are the subject of a standard of identity that requires the addition of folic acid; to provide for its addition to breakfast cereals on a per serving basis; to permit its use in infant formulas, medical foods, and foods for special dietary use; and to incorporate specifications for folic acid consistent with those in the Food Chemicals Codex. This action is being taken to ensure that the amount of folic acid that all segments of the population are reasonably expected to consume is safe under the Federal Food, Drug, and Cosmetics Act (the act) and to implement Public Health Service's (PHS) recommendation to increase folic acid intake by women of childbearing age, thereby reducing the risk of pregnancies affected by neural tube defects (NTD's).

**DATES:** Effective March 5, 1996; written objections and requests for a hearing by April 4, 1996. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication in 21 CFR 103.35(d)(3)(v), effective March 5, 1996.

**ADDRESSES:** Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Dennis M. Keefe, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3090.

**SUPPLEMENTARY INFORMATION:****I. Background**

In the Federal Register of October 14, 1993 (58 FR 53312), FDA proposed to amend the regulation that establishes safe conditions of food use for folic acid, § 172.345 (21 CFR 172.345)). In the proposed rule, which was entitled "Food Additives Permitted for Direct Addition to Food for Human Consumption; Folic Acid (Folacin)," FDA said that it intended to amend § 172.345 to: (1) Set limitations on the

use of folic acid on a per serving basis, in accord with the Nutrition Labeling and Education Act of 1990; (2) allow for the addition of folic acid in foods for which standards of identity exist, where such standards permit the addition of folic acid; (3) restrict to breakfast cereals the foods for which standards of identity do not exist, to which folic acid may be added; (4) continue to permit the use of folic acid in infant formulas, dietary supplements, and foods for special dietary use; and (5) incorporate specifications for folic acid consistent with those in the Food Chemicals Codex.

Interested persons were given until December 13, 1993, to comment on the proposal. FDA received 59 letters, each containing one or more comments, from consumers, members of the Folic Acid Subcommittee of FDA's Food Advisory Committee, the United States Pharmacopeial Convention, Inc., consumer interest groups, food manufacturers, trade associations, and dietary supplement manufacturers. Most comments generally supported the proposed amendments. Some comments suggested modifications of various provisions of the proposed rule or requested clarification of certain issues. A number of comments were received that were more appropriate to other dockets, and these were forwarded to the appropriate dockets (Docket Nos. 91N-100H or 91N-100S) for response. A summary of the comments and the agency's responses are presented in section II of this document.

**II. Comments to the Proposal****A. Safe Upper Limit**

As part of FDA's implementation of the PHS recommendation that women of childbearing age consume 400 micrograms (µg) of folic acid per day to reduce their risk of a pregnancy affected by an NTD (Ref. 1), FDA initiated this proceeding, as well as a rulemaking to authorize a health claim on the relationship between folate and NTD's and a rulemaking to require the addition of folic acid to certain standardized cereal-grains. As part of FDA's rulemaking to authorize a folate health claim, the agency found it necessary to address the issue of the safe upper limit of daily folate intake. In the health claim proceeding, FDA was confronted with all of the issues related to a safe upper limit that have been presented in this proceeding. Thus, FDA's response to the comments that addressed the safe upper limit for folic acid intake in the present rulemaking draws largely on the agency's response to similar comments as laid out in a final rule authorizing a

health claim about the relationship of folate and neural tube defects published elsewhere in this issue of the Federal Register.

The agency's overriding goal in this food additive rulemaking is to ensure that the amount of folic acid that all segments of the population are reasonably expected to consume is safe under section 409(c)(3)(A) and (c)(5)(A) of the act (21 U.S.C. 348(c)(3)(A) and (c)(5)(A)), while concurrently aiding compliance with the PHS recommendation on folate and NTD's by increasing the folate content of the U.S. food supply.

The agency noted in the final folate health claim rule of January 6, 1993 (58 FR 2606 at 2612), and the folate health claim final rule published elsewhere in this issue of the Federal Register, that there may be risks attendant upon increased consumption of folate for some groups in the population. At the present time, the potential adverse effect for which there is the most evidence is a masking of anemia in persons with vitamin B<sub>12</sub> deficiency, while severe and irreversible neurologic damage may progress. There is currently no way to determine how many persons in the general U.S. population have undiagnosed vitamin B<sub>12</sub> deficiency, and thus, how many are potentially at risk of developing pernicious anemia. However, marginal vitamin B<sub>12</sub> nutritional status is not uncommon in the U.S. population (58 FR 53254 at 53266 to 53268), and it is observed not only in persons with pernicious anemia from an inability to absorb dietary vitamin B<sub>12</sub> but also in approximately 10 to 20 percent of elderly persons, more than 25 percent of demented patients, 15 to 20 percent of acquired immune deficiency syndrome (AIDS) patients, and 15 to 20 percent of patients with malignant diseases.

The agency further noted that other groups may be at risk from excessive intakes of folate. These other groups include pregnant women (with the potential for high levels of free folic acid affecting the embryo during early gestation) and persons on medications (the effectiveness of which could be adversely affected by high dietary folate intakes) used in the treatment of various cancers, psoriasis, rheumatoid arthritis, and bronchial asthma). Throughout its folate rulemaking proceedings, FDA evaluated the safety of high intakes of folate for all of these potentially at-risk groups. In its folate health claim final rule published elsewhere in this issue of the Federal Register, the agency described how it had reached its decision that 1 mg of total folate per day was the safe upper limit of intake.

In the folate health claim proposed rule (58 FR 53254, October 14, 1993), the agency provided data demonstrating the difficulty of concurrently achieving the PHS recommended increase in folate intake for all women of childbearing age without raising folate intakes of other segments of the population to unsafe levels. Thus, the agency recognized the significance of the proposed upper limit for daily folate intake in limiting the ability of fortification of the food supply alone to enable all women of childbearing age to achieve the PHS recommendation on folate intake. The agency also noted that there is a general paucity of evidence on the safety of daily folate intakes above 1,000 µg (1 mg). Therefore, in the folate food additive proposal, FDA specifically requested comments and data on the use of 1 mg per day total folate as a safe upper limit for establishing restrictions on food additive uses of folic acid. FDA further noted that the 1 mg daily safe upper limit for folate intake may need to be modified if data became available to support such a decision. Several comments supported FDA's tentative conclusion of 1 mg total dietary folate per day as the safe upper limit because they felt that the 1 mg per day limit is based on the best available data. As described below, other comments felt that this level was either too high or too low.

#### 1. Folate intakes of 1 mg or Less Daily

Several comments contended that current scientific knowledge is insufficient to set the safe upper limit at 1 mg folate per day, and that perhaps the safe upper limit may actually be lower than 1 mg folate per day. These comments cited published studies suggesting that 500 µg folic acid per day may mask the anemia of vitamin B<sub>12</sub> deficiency and urged that FDA set the safe upper limit below 500 µg folic acid per day. None of the commenters provided any new data to support their arguments.

FDA disagrees with those comments that contended that the safe upper limit of intake of 1 mg folate daily is too high, and that the limit should be set at a lower level. In its proposed folate health claim rule (58 FR 53254 at 53266 to 53270, October 14, 1993), FDA stated that it was aware that several published case reports suggest that there is evidence of masking of pernicious anemia in patients who consumed supplements that provided less than 1 mg folic acid daily. FDA was also aware of limited reports of masking of the anemia of vitamin B<sub>12</sub> deficiency at levels as low as 250 µg folic acid daily. These reports were the basis for the

agency's amendment, in the Federal Register of October 17, 1980, to its drug regulation on the therapeutic uses of folic acid (45 FR 69043 at 69044). In that instance, the agency required that the labeling of oral and parenteral preparations of folic acid include a "Precautions" statement that "Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive" (see discussion in proposed health claims rule, 58 FR 53254 at 53257, October 14, 1993).

FDA, as part of its review of the scientific literature and its discussions with the Folic Acid Subcommittee, carefully considered the reports of masking at relatively low levels of folate. In its folate health claim proposal, FDA noted that the effects of intakes of less than 1 mg are infrequent, suboptimal, and less predictable than those occurring at higher intakes (58 FR 53254 at 53267, October 14, 1993).

A safe upper limit of daily folate intake of 1 mg for persons with vitamin B<sub>12</sub> deficiency was discussed by experts during a Centers for Disease Control and Prevention (CDC) workshop on surveillance for adverse effects of increased folic acid intakes. Those experts stated that there was little likelihood of problems at daily intakes lower than 1 mg (Ref. 2).

Most commenters with expertise in folate and vitamin B<sub>12</sub> metabolism and nutrition also supported a safe upper limit of 1 mg folate daily based on their scientific knowledge and clinical experiences (see folate health claim final rule published elsewhere in this issue of the Federal Register). Moreover, a safe upper limit of 1 mg folate daily is consistent with the current Reference Daily Intakes (RDI's) for folate (i.e., 400 µg daily for the general population and 800 µg daily for pregnant women, levels that were the same as the U.S. RDA's that were used as early standards for nutrition labeling (Ref. 3)) and is consistent with the 1992 PHS recommendation for women of childbearing age (Ref. 1).

Therefore, FDA concludes that for those with vitamin B<sub>12</sub> deficiency, there is little likelihood of problems if daily folate intakes are 1 mg or less. Moreover, FDA received no comments that disagreed with the agency's tentative conclusions that daily folate intakes of 1 mg or less are safe for pregnant women and for persons on medications whose effectiveness could be adversely affected by high folate intakes. Thus, FDA concludes that there is a reasonable certainty of no harm from a daily intake of up to 1 mg folate.

## 2. Folate Intakes Above 1 mg Daily

Other comments asserted that FDA's tentative conclusion of a safe upper limit of intake of 1 mg daily was too low. These comments contended that there is no evidence that folic acid intakes of 1.5 to 2 mg per day would result in any untoward effects and recommended that FDA set the safe upper limit at 1.5 to 2 mg folic acid per day. Another comment opined that setting the safe upper limit for folate intake at 1 mg per day is "arbitrary" and "paranoid." One comment claimed that the 1 mg limit is inappropriate because it is not based on substantive medical data. Several comments claimed that there is no evidence to suggest that folic acid doses at 1 mg per day are toxic. One comment argued that "[t]here is no toxicity for folic acid per se," and that "[t]he fact one mg. is needed to treat megaloblastic anemia really represents a floor. It does not speak to the intakes of Americans from food and fortification and supplements. Because Americans are laggards in their intake, a relative ceiling of 2 mgs. is not likely to be reached." This comment argued that, because the food bioavailability of folacin is fair but not excellent, fortificant and supplement intakes of folic acid are not likely to exceed one mg. None of these comments provided data to support their views.

Several comments focused on the safety of high folate intakes for pregnant women. These comments suggested that concerns about the safety of high intakes of folate in pregnant women were unfounded. In support of this contention one comment claimed that "\* \* \* millions of pregnant women have safely consumed prenatal vitamins with 1 mg of folic acid in addition to their diet over the past 15-20 years." Several comments questioned why FDA set the safe upper limit at 1 mg per day while the United Kingdom (UK) was recommending a much higher limit of 5 mg folic acid per day.

Other comments focused on FDA's concern about the absence of data on safe use for persons with marginal vitamin B<sub>12</sub> nutritional status. One comment asserted that FDA overstated the issue of the masking of B<sub>12</sub> deficiency by folate. Another comment claimed that a hematologic response to folic acid in dosages between 1 mg and 5 mg per day appears to occur in persons with clinical vitamin B<sub>12</sub> deficiency, but the frequency, magnitude, and duration of this response is unknown. The comment also stated that it is not known whether this hematological response could lead to a delay in the diagnosis of vitamin

B<sub>12</sub> deficiency. While agreeing that the masking of pernicious anemia is a concern, these comments argued that there is evidence that a substantial proportion of persons with pernicious anemia do not present with anemia before neurological symptoms. Therefore, these comments argued, these individuals would suffer the effects of undiagnosed pernicious anemia with or without folic acid supplementation. These comments did not provide any new data to support their view.

In proposing the safe upper limit at 1 mg folate per day, FDA carefully considered the available evidence on the safety for all segments of the population that might be placed at risk if folate intakes were to become excessively high. In response to the proposal, the agency did not receive any comments that provided data relating to the safety of long-term intakes of folate at levels above 1 mg per day for any of the groups considered at potential risk from increased intakes. FDA notes that both the Folic Acid Subcommittee and the Food Advisory Committee expressed concerns about the lack of information to support the safety of long-term daily intakes at levels above 1 mg (Ref. 4). The Food Advisory Committee also expressed concern about the lack of information on the size of the population potentially at risk from increased intakes of folate.

The agency is not aware of data that establish the safety of long-term intakes of folate above 1 mg per day. The absence of any data allowing systematic evaluation of intakes above this level means that potential risks and at-risk groups cannot be adequately defined or described. FDA notes that most folate and vitamin B<sub>12</sub> experts submitting comments were concerned about the lack of documentation of safety of long-term daily intakes of folate above the level of 1 mg per day. In addition to expressing safety concerns regarding those with low vitamin B<sub>12</sub> status, experts cited uncertainties about the effects of increased folate intakes by young children and the unknown physiological significance of circulating free folic acid in the blood, particularly in pregnant women. In its folate health claim proposed rule (58 FR 53254 at 53269, October 14, 1993), the agency summarized evidence from the scientific literature that high levels of free folic acid are not normally found in the circulation, and that folic acid is concentrated in crossing the placenta and accumulates in fetal tissues. At that time, the agency noted that no information was available to ascertain whether developing neural tissue is

protected from the neurotoxic effects of very high circulating levels of free folic acid. Neither these issues nor issues related to long-term folate intakes of greater than 1 mg daily by other risk groups were addressed in the comments that the agency received.

The agency finds that the comments that suggested that there is evidence of safe use of high intakes of folate by pregnant women are misleading and erroneous. The agency disagrees with comments asserting that folic acid at doses of 4 mg per day have been extensively studied in pregnant women and are without toxic effects. The agency recognizes that pregnant women take prenatal supplements that usually contain 800 µg of folic acid, and that such supplements have been in use for many years. FDA notes, however, that while there is no evidence that 800 µg of folic acid per day (i.e., the U.S. RDA level for pregnant or lactating women) is unsafe for this group, such dosages are usually taken only during the second and third trimesters of pregnancy, or during lactation, to meet specific nutritional needs for limited periods of time and are usually taken under a physician's supervision. FDA further notes that the Institute of Medicine has stated that the safety of large doses of folic acid in pregnant women has not been systematically determined (Ref. 5).

FDA also disagrees with the comments that stated that the recommendations of the government of the UK are directly relevant to inferring that 5 mg daily is a safe level of intake for pregnant women. FDA notes that these comments fail to reveal the full content of the UK recommendations (Ref. 6). The UK government made two recommendations relating daily folate intake to women of child-bearing age. The first recommendation is for health care professionals to prescribe a dietary supplement containing 4 or 5 mg (4,000 or 5,000 µg) folic acid daily until the 12th week of pregnancy to women who have already had a pregnancy affected by a neural tube birth defect and, therefore, are at a particularly high risk for another affected pregnancy. The second recommendation is that women of child-bearing age, who have not had a previous pregnancy affected by a neural tube defect and who are likely to become pregnant, should increase their intakes of folate-rich foods and take a dietary supplement containing 400 µg folic acid daily. The supplement use is recommended from the start of attempting to conceive until the 12th week of pregnancy. Clearly, the UK recommendation for women in the general population is the relevant recommendation to this rulemaking

rather than the recommendation for the use of high potency supplements, by prescription, for women at high risk of an affected pregnancy. Moreover, the UK recommendation for women in the general population is consistent with the PHS recommendation, to which FDA subscribes. Finally, and most significant to this rulemaking, the UK recommendations do not directly address the safety of fortification for the entire food supply. FDA, therefore, finds that, contrary to the suggestion in the comment, the UK's folate intake recommendations for women anticipating pregnancy, but who have not had a history of a prior affected pregnancy, are consistent with FDA's conclusions of safe intakes for pregnant women.

FDA also disagrees with the comment that asserted that folic acid at doses of 4 mg per day has been extensively studied in pregnant women, and that such doses are without toxic effects. In the only study utilizing 4 mg folic acid per day, the Medical Research Council trial, about 910 women took supplements containing 4 mg of folic acid from the time of randomization into the trial until the 12th week of pregnancy (Ref. 7). The authors of this study concluded that, although this trial had sufficient statistical power to demonstrate the efficacy of the intervention, it did not have sufficient power to answer the question of safety for public health purposes. Consequently, this study does not provide a basis on which to determine whether the chronic use of 4 mg per day of folic acid by pregnant women is safe. The agency is not aware of any other studies on the effect of daily folate intakes of 4 mg in pregnant women, or of any other data or information that would persuade the agency that 4 mg folate per day is the appropriate safe upper limit of intake for pregnant women.

FDA is also not convinced by the comments on masking of the anemia of vitamin B<sub>12</sub> deficiency that a higher value for a safe upper limit of folate intake is appropriate. As stated in the food additive proposed rule (58 FR 53312, October 14, 1993), one of the safety concerns associated with high intakes of folate is the potential for masking the anemia associated with vitamin B<sub>12</sub> deficiency which may delay accurate diagnosis and prompt treatment of this problem while neurologic damage progresses. The symptoms of vitamin B<sub>12</sub> deficiency include both hematologic and neurologic effects. While the hematologic effects of vitamin B<sub>12</sub> deficiencies are reversible, the

associated neurologic effects may be irreversible depending on how far they have progressed before detection and treatment. Any increase in the potential for masking the hematologic effects of vitamin B<sub>12</sub> deficiency may compromise prompt and effective treatment, thereby making irreversible neurologic damage more likely.

The scientific literature describing the effects of intakes of folic acid between 1 and 5 mg per day is very limited. Nonetheless, FDA disagrees with the comments that asserted that there is no evidence of untoward effects of daily folate intakes of 1.5 to 2 mg per day, and that 5 mg per day should be identified as the safe upper limit of intake.

The literature describing the effects of daily intakes of 1 to 5 mg folic acid includes three uncontrolled intervention trials involving 15 persons (Refs. 8, 9, and 10) and 16 case reports (Refs. 11, 12, 13, 14, 15, and 16). These reports represent a very small data base, with information from a total of only 31 individuals. Moreover, the agency notes that, among these data, exposures of 9 individuals to daily intakes of 1 to 5 mg folic acid lasted for less than 30 days (e.g., Refs. 9, 11, 12, and 17). These short-term reports are inadequate for assessing the safety of life-long exposures. FDA notes, however, that hematological responses that could lead to a delay in the diagnosis of vitamin B<sub>12</sub> deficiency were observed in 9 of the 16 patients (i.e., in more than 50 percent) whose daily oral intakes of folic acid were in the range of 1 to 5 mg and continued for 1 month or more (Refs. 8, 11, 12, 14, and 16). Thus, the scientific literature, although limited, shows that approximately half of the patients with pernicious anemia associated with vitamin B<sub>12</sub> deficiency responded to folate at doses between 1 and 5 mg per day when they are given the vitamin for relatively short periods of time (e.g., several months).

FDA also is not convinced by the comments that noted that adverse effects of high intakes of folate with respect to vitamin B<sub>12</sub> deficiency can be detected with clinical care and that the issue of masking of vitamin B<sub>12</sub> deficiency predated modern clinical nutrition. FDA is aware that, in many instances, the adverse effects of increased folate intake associated with the masking of the anemia of vitamin B<sub>12</sub> deficiency can be detected with clinical care but disagrees that clinical care alone is sufficient to ensure a reasonable certainty of no harm should the intake of folate exceed 1 mg folate per day. The agency notes that measurements of vitamin B<sub>12</sub> status are not performed on a routine basis by

physicians, and that there is no way to systematically determine how many people in the United States have undiagnosed vitamin B<sub>12</sub> deficiency and thus might be at risk from increased intake of folate. The agency noted in the January 6, 1993, folate health claim final rule (58 FR 2606 at 2615) that significant percentages of the elderly, demented patients, AIDS patients, and patients with malignant diseases have subnormal vitamin B<sub>12</sub> levels without having any of the classical manifestations of vitamin B<sub>12</sub> deficiency. It has been reported, in a large study (n = 548) that the prevalence of vitamin B<sub>12</sub> deficiency is greater than 12 percent among free-living elderly Americans (Ref. 18). In addition, 5 to 10 percent of all patients, regardless of age or clinical status, are found to have low serum vitamin B<sub>12</sub> levels (58 FR 2606 at 2615, January 6, 1993). Little is known about whether folate supplementation would have any adverse effect on such persons, who are far more numerous in the U.S. population than are persons with pernicious anemia.

The argument that adverse effects in persons with vitamin B<sub>12</sub>-related problems can be identified with clinical care fails to consider whether such persons, who may be unaware of their vitamin B<sub>12</sub> status, would recognize an adverse effect as being the result of increased folate intake, and whether they would seek medical attention if such an effect occurred. There is no reason to conclude that they would. Thus, the agency concludes that the argument that adverse effects in persons with vitamin B<sub>12</sub>-related problems can be identified with clinical care does not provide a sufficient basis for the agency to conclude that increasing the safe upper limit of intake provides a reasonable certainty of no harm.

In developing its proposed rules, FDA was aware of the contentious nature of the proposed 1 mg folate per day upper limit and specifically asked for data on this issue. This topic was also extensively discussed by FDA's Folic Acid Subcommittee and the full Food Advisory Committee (Refs. 4 and 19). No data were submitted in any of the comments that addressed the issue of the safety of intakes above 1 mg per day either for persons in the general population or for any of the groups identified as potentially at risk from increased folate intakes. The agency also notes that its position regarding use of 1 mg folate per day as the safe upper limit of daily intake was supported by all comments from individuals with known expertise in folate and vitamin B<sub>12</sub> metabolism and related diseases.

Because there are inadequate data and information on the safety of consuming more than 1 mg folate per day, the agency finds that it cannot conclude that there is a reasonable certainty of no harm to persons who consume more than 1 mg folate per day. In the absence of safety data on daily intakes of folate above 1 mg per day, the agency is unable to adequately define the nature, or assess the magnitude, of potential risk from increased folate intakes. Therefore, the agency concludes that, because of the lack of evidence to support the safety of intake at levels greater than 1 mg folate daily, and the potential for serious harm to some persons from such intakes, the safe upper limit for daily folate intakes is appropriately set at 1 mg, the highest intake level that meets the safety standard for food additives that there is a reasonable certainty of no harm from use of the additive.

FDA finds that 1 mg per day as the safe upper limit for folate intake is supported by: (1) The totality of the available scientific evidence and the views expressed by experts with recognized expertise in folate and vitamin B<sub>12</sub> nutrition and metabolism, that there are no data to ensure that adverse effects are not likely to occur at daily intakes above 1 mg (Refs. 2, 4, 19, and 20); (2) the PHS recommendation that folate intake of women of childbearing age should not exceed 1 mg per day (Ref. 1); and (3) the Folic Acid Subcommittee's use of 1 mg of total folate per day as a safe upper limit guide when considering fortification strategies.

The agency also is aware, however, of the rapidly evolving and potentially significant research suggesting a possible link between folate intakes and reduced risk of heart disease. The agency notes that a recent expert workshop sponsored by the National Heart, Lung, and Blood Institute of the National Institutes of Health reviewed the state-of-the art science in this area (Ref. 21). The expert working group found that the currently available data, while highly suggestive of a relationship, were insufficient to demonstrate the validity of this hypothesis. Nonetheless, FDA intends to monitor and review new data and information on both the safety of daily folate intakes at levels above 1 mg daily and on the potential need for improving the folate nutritional status of large segments of the U.S. population. Should persuasive evidence emerge that provides a reasonable certainty that daily intakes of folate at higher levels are safe, the agency will take action to

modify the 1 mg per day safe upper limit for daily folate intake.

#### *B. Concurrent Vitamin B<sub>12</sub> Addition*

One comment recommended requiring the addition of vitamin B<sub>12</sub> to all foods containing added folic acid as a means to alleviate some of the concerns about the masking of the effects of vitamin B<sub>12</sub> deficiencies. Another comment claimed that many dietary supplements contained 100 percent of the RDI for vitamin B<sub>12</sub> as well as 100 percent of the RDI for folic acid and asserted that this level of vitamin B<sub>12</sub> should allay the concerns about masking vitamin B<sub>12</sub> deficiencies.

FDA is aware that very high oral doses of vitamin B<sub>12</sub> (e.g., about 1 mg; 500-times the RDI for this vitamin) have provided effective treatment for some persons with pernicious anemia (Ref. 22). These findings have led some scientists to suggest that high doses of vitamin B<sub>12</sub> could be added to foods and dietary supplements fortified with folic acid to reduce the potential for adverse effects in persons with vitamin B<sub>12</sub> deficiency.

This suggestion was discussed during a meeting on surveillance for adverse effects of increased intakes of folate organized by CDC (Ref. 2). Several experts noted that even if an individual has pernicious anemia because of vitamin B<sub>12</sub> malabsorption, they are able to absorb a small amount of oral vitamin B<sub>12</sub> (about 1 to 2 percent). Several experts, however, suggested that one possible question about using foods or food products containing added vitamin B<sub>12</sub> is that in the presence of other nutrients (e.g., vitamin C, thiamin, iron), vitamin B<sub>12</sub> may be converted into analogs, some of which may have antivitamin B<sub>12</sub> activity. The participants in this meeting noted the paucity of data about this matter. There were no conclusions or recommendations by this expert group on these issues.

In the folate health claim proposal of October 14, 1993 (58 FR 53254 at 53280), the agency discussed the issue of whether high doses of vitamin B<sub>12</sub> should be added to foods or supplements fortified with folic acid to reduce the potential for adverse effects in persons with vitamin B<sub>12</sub> deficiency. The agency requested comments, and specifically data, on the appropriateness, potential effectiveness, and safety of such fortification. The agency did not receive any data or other information on this issue.

Because data are not available that address the safety of simultaneous fortification of foods or dietary supplements with both folate and

vitamin B<sub>12</sub>, the agency cannot establish a level of oral vitamin B<sub>12</sub> that is safe for the general population, safe for persons with vitamin B<sub>12</sub>-related problems, and sufficiently high to protect persons with vitamin B<sub>12</sub>-related problems from the adverse effects of increased intakes of folate. Furthermore, FDA notes that, because difficulty in absorbing oral vitamin B<sub>12</sub> is the primary reason for inadequate vitamin B<sub>12</sub> nutrition in many persons, the amount of vitamin B<sub>12</sub> to be added would likely need to be very high, perhaps up to 500 times the RDI. Questions regarding the appropriateness, potential effectiveness, and safety of such an approach remain unanswered.

Given that vitamin B<sub>12</sub> deficiency, including pernicious anemia, is a serious condition, which if untreated can lead to irreversible neurological damage, patients with pernicious anemia, and others at risk of vitamin B<sub>12</sub> deficiency, should be diagnosed, treated, and monitored by a physician (Ref. 22). Moreover, the addition of both vitamin B<sub>12</sub> and folic acid to a food is not relevant to other potential safety issues associated with high folate intakes (e.g., high intakes in pregnant women and adverse interactions in persons on some medications). Therefore, the agency rejects the suggestion that it require the addition of vitamin B<sub>12</sub> to all foods containing added folic acid because there is not sufficient information to demonstrate that the addition of vitamin B<sub>12</sub> whenever folic acid is added will be effective for its intended purpose and will ensure the safety of the use of folic acid.

#### *C. Folate Versus Folic Acid*

Several comments supported FDA's proposal to fortify certain cereal-grain products based on a safe upper limit for total folate rather than folic acid. Some comments stated that the use of total folate as opposed to only added folic acid to set the safe upper limit of intake was advisable because this approach provides an additional safety factor. Other comments recommended that the safe upper limit should be based solely on added folic acid and not total folate intake.

In support of establishing the safe upper limit based on folic acid intakes, one comment claimed that the 1 mg limit should be based on folic acid rather than folate because the bioavailability of folate is fair but not excellent. One comment argued that using folic acid rather than folate as the benchmark for measuring the safe upper limit of total folate intake is consistent with FDA's historical treatment of the

distinction between folic acid and folate. The comment pointed out that in 1971, for example, FDA concluded that "[f]olic acid especially in doses above 1.0 mg daily may obscure pernicious anemia \* \* \*" (36 FR 6843, April 7, 1971). According to this comment, in 1979, FDA warned that for products containing 1 mg folic acid "[t]he use of folic acid for treatment of anemia without the direction of a physician may be dangerous." (44 FR 16126 at 16149, March 16, 1979.)

Several comments questioned why FDA proposed to establish the safe upper limit on a folate basis, rather than on a folic acid basis, given the fact that the human trials were run with folic acid, and there is no evidence of food folate reducing the incidence of NTD's.

Another comment recommended that the safe upper limit be established on a folic acid basis because:

\* \* \* (1) all evidence relative to the delay in diagnosis of vitamin B<sub>12</sub> deficiency at consumption levels of 1,000 mcg and above, however equivocal, derives from persons who took *folic acid* supplements orally or received folic acid parenterally and who were simultaneously consuming folates from their diets, and, (2) for years, the cut point between 'over the counter' and prescription *folic acid* supplements has been 1,000 mcg. FDA's 1971 drug use/safety regulation governing oral and parenteral usage of folic acid (36 FR 6843) stated that "folic acid especially in doses above 1.0 mg daily may obscure pernicious anemia in that hematologic remission may occur while neurological manifestations remain progressive."

As discussed previously and in the proposed rule (58 FR 53312, October 14, 1993), FDA is aware of the effect on the choice of a fortification option if the safe upper limit were established based on total folate rather than the added form of the vitamin, folic acid. FDA notes that the distinction between "synthetic folic acid," referring only to folic acid, and "folate," referring only to naturally occurring food folates, with respect to the 1 mg estimate of safe daily intake is an artificial one and is not consistent with what is known about the metabolic interrelatedness and substitutability of a variety of folate vitamin forms.

The agency acknowledges that evidence relative to the masking of the anemia of vitamin B<sub>12</sub> deficiency has been obtained from persons who consumed or were treated with synthetic folic acid. However, these individuals were also consuming unmeasured quantities of folate from foods. Thus, total daily folate exposures were unknown. The extent to which variations in background food folate intakes affected the variable responses, in terms of masking effects, cannot be

determined. The absence of data on this issue means that it is not possible to conclude that only added folic acid is responsible for any masking effects.

Moreover, the agency notes that studies in vegetarians can provide some insights into the question of whether high intakes of folates from food sources alone can have adverse effects in persons with poor vitamin B<sub>12</sub> status. Vegetarians present a model group for evaluating this question because their diets are very low in vitamin B<sub>12</sub> (because animal foods are the sole dietary source of vitamin B<sub>12</sub>) and usually very high in foods rich in folate (e.g., fruits, vegetables and legumes). Thus, vegetarians are at risk of developing vitamin B<sub>12</sub> deficiency in the presence of high folate intakes. In one study of vegetarians, the authors reported that megaloblastic anemia (i.e., the type of anemia associated with vitamin B<sub>12</sub> deficiency) is rarely encountered in Caucasian vegetarians and vegans (Ref. 23). This study also reported that the folate content of diets of vegan children aged 6 to 13 years was twice as high as that of omnivorous children aged 7 to 12 years. When infants of vegetarian mothers developed vitamin B<sub>12</sub> deficiency, they usually presented first with neurological signs and symptoms rather than anemia. Another article reported that studies conducted over several decades in vegetarian populations have all indicated that major damage to myelin synthesis (i.e., synthesis of the covering of nerves) occurs with only minor hematopoietic damage (i.e., inability to synthesize red blood cells, resulting in anemia) (Ref. 24). This report also found generally higher red cell folate in persons with greater myelin damage of the type that only vitamin B<sub>12</sub> deficiency produces than in persons with greater hematologic damage (i.e., anemia). These studies are suggestive that high food folate intakes alone can mask early hematologic symptoms of vitamin B<sub>12</sub> deficiency in vegetarians, thus, suggesting that food folates and synthetic folic acid are each capable of causing masking effects.

These observations support the view that a safe upper limit of daily intake is more accurately based on total folate intake than on just intake of synthetic (or added) folic acid. Under conditions in which vitamin B<sub>12</sub> utilization or intake is limited, either synthetic folic acid or food folate may cause masking of vitamin B<sub>12</sub>-related anemia, and these two sources appear to be additive.

FDA also disagrees with the comments that the historical concern with safety of folate intakes for drugs, as well as for FDA's food additive

regulations, was limited only to synthetic folic acid. The agency notes that the commenters' references to FDA's 1971 drug regulation in which intakes of synthetic folic acid above 1 mg daily were stated to cause masking of anemia related to vitamin B<sub>12</sub> deficiency are misleading in that they fail to note that in 1980, FDA revised the 1971 drug regulation to require a warning statement that intakes as low as 0.1 mg daily may obscure pernicious anemia (45 FR 69043 at 69044, October 17, 1980). Clearly, for the food supply, a safe upper limit of intake of 0.1 mg would be inadequate to provide the known folate nutritional requirements of the U.S. population. Thus, considerations in drugs that are intended for the treatment of persons with diagnosed diseases and health-related conditions are not necessarily directly applicable to questions of food safety.

FDA further finds that suggestions that the historical examination of food additive regulations dealt only with synthetic folic acid are not helpful. Food additive regulations on folate addition to foods necessarily specify that the added form is synthetic because that is the only form that can be a food additive. On the other hand, it is common practice when evaluating the safety of an added food ingredient to consider the safety within the context of total dietary exposures, regardless of source.

As to comments on possible differences in bioavailability between food sources and synthetic sources of folic acid and the potential of these differences to affect safety considerations, FDA discussed this issue in its proposed health claim rule (58 FR 53254 at 53273 to 53274). FDA tentatively concluded that the issue of bioavailability is complex, and that no systematic data are available on many of the factors that affect bioavailability. FDA was not aware of any meaningful way to factor bioavailability into fortification scenarios or, by extension, into evaluations of safety. FDA received no new data on this matter. Therefore, FDA has no basis on which to factor possible differences in bioavailability of synthetic, as opposed to food, folates into its determination of the safe upper limit of folate intakes.

Significantly, the use of a distinction between folic acid and folate for the purposes of establishing a safe upper limit of folate intake was not supported by any expert group that the agency consulted during this rulemaking proceeding or by comments from experts in folate and B<sub>12</sub> metabolism and related diseases (Refs. 2, 4, and 19).



Nor was it supported by any of the folate or vitamin B<sub>12</sub> experts who submitted written comments to the record. FDA received no new data or compelling arguments in this regard. Therefore, the agency concludes that the safe upper limit of daily intake should be based on total folate intake (i.e., on consumption of folate from all sources).

#### *D. Breakfast Cereals*

Several comments supported the proposal to limit the fortification of breakfast cereals to 100 µg per serving. One comment supported the proposed rule's distinction between the consumption of dietary supplements and breakfast cereals, noting that:

The document appropriately makes the distinction between breakfast cereal and vitamin supplements noting that some persons may consume many more than one serving of breakfast cereal per day.

In contrast, however, another comment argued that:

\* \* \* the potential for overconsumption of folic acid is greater for dietary supplements in pill/tablet/capsule form than for supplement cereals. Supplement cereal consumption is self-limiting in light of volume and caloric considerations. In contrast, smaller supplements have the potential to be consumed excessively, for example, by adults using a multivitamin/mineral product to increase vitamin C intake to combat a cold, or by children, with the potential result of iron toxicity.

Several comments recommended that currently marketed breakfast cereals containing 400 µg per serving folic acid should be allowed to continue to be formulated at this level. One breakfast cereal manufacturer argued that allowing dietary supplements to contain the full RDI level of folic acid while limiting the folic acid added to breakfast cereal to 25 percent of the RDI did not seem to be based on any scientific rationale:

If 100% RDI is a safe level for a vitamin supplement in tablet form, it surely is a safe level in a food form. In fact, food is potentially a safer alternative since the consumption is self-limiting; whereas there is greater potential for over consuming supplements in tablet form.

Several comments stated that they did not understand how FDA could reduce the level of added folic acid in breakfast cereals and still implement the PHS recommendation to have women of childbearing age consume 400 µg folic acid per day. Other comments argued that FDA should allow some breakfast cereals to contain 100 percent of the RDI for folic acid per serving as an alternative to taking dietary supplement tablets.

Still other comments argued that FDA should not make a regulatory distinction between dietary supplements in conventional and unconventional food forms. The comments asserted that both should be allowed to provide 100 percent of the daily value of folic acid.

One comment suggested that for breakfast cereals to contain 100 percent of the RDI for folic acid, they must contain 100 percent of the RDI for at least 10 vitamins for which RDI's have been determined to preserve their status as rationally balanced supplement products.

In the proposal, FDA tentatively concluded that if cereal-grain products were fortified at 140 µg folic acid per 100 g, the addition of folic acid to breakfast cereals should be limited to 100 µg folic acid per serving. FDA stated that fortification of all breakfast cereals to 400 µg folic acid per serving would result in the estimated daily intake of folate among significant portions of the population exceeding the safe upper limit of 1 mg folate per day.

FDA recognizes that fortification of some breakfast cereals at 400 µg folic acid per serving provides women of child-bearing age flexibility to meet the PHS recommendation that such women consume 400 µg of folic acid per day as a means to reduce their risk of having a pregnancy affected by an NTD. FDA emphasizes that the estimates of folate consumption presented in the health claims proposal (58 FR 53295, October 14, 1993) were based on calculations that assumed all breakfast cereals would be fortified at 0, 100 µg, or 400 µg folic acid per serving. As discussed in the proposal, most breakfast cereals are fortified at 100 µg folic acid per serving, and only 3 to 6 percent of breakfast cereals are fortified at 400 µg folic acid per serving (Nielsen Scantrack Data, A.C. Nielsen Marketing Research, Inc., Cherry Hill, New Jersey).

FDA has no basis to conclude that the current market distribution of breakfast cereals fortified at 400 µg folic acid per serving will substantially change as the result of the authorization of a health claim on the relationship of folate to NTD's. In fact, the agency notes that the health claim on the relationship between folate and NTD's may be included in the labeling of foods that are good sources of folate (40 to 76 µg folic acid per serving). Because most breakfast cereals contain folic acid at levels (100 µg folic acid per serving) that permit them to bear this health claim, there is no need for breakfast cereal manufacturers to increase their level of folic acid fortification to qualify to bear the claim.

Moreover, FDA has provided in 21 CFR 101.79(c)(2)(i)(G) that the health claim for folate and NTD's cannot state that a specified amount of folate per serving from one source is more effective in reducing the risk of NTD's than a lower amount per serving from another source. Thus, the health claim regulation provides no incentive for increasing the level of folic acid fortification in breakfast cereals.

Therefore, given the small number and limited market share of breakfast cereals that are fortified with 400 µg of folic acid per serving, the lack of incentive for there to be any significant increase in this number, and the fact that, if used appropriately, breakfast cereals can contribute to a healthful diet and provide flexibility for women in selecting foods to meet the PHS recommendation, FDA has concluded that it is not necessary to limit the addition of folic acid to breakfast cereals to 100 µg folic acid (25 percent of the RDI) per serving. FDA has determined that addition of up to 400 µg folic acid per serving in breakfast cereals is safe as long as this practice does not become widespread. FDA intends to monitor the marketplace, however, and should the proportion of breakfast cereals fortified at 400 µg folic acid change substantially, FDA may find it necessary to reconsider this conclusion.

#### *E. Fruit Juice Replacements*

One comment recommended that fruit juice replacements be permitted to add folic acid at 20 percent of the RDI.

FDA has considered this recommendation in light of its efforts towards implementation of the PHS recommendation and establishing safe conditions of use for folic acid.

In examining options for providing folate to women of childbearing age through food fortification, the agency considered various options including allocation of folate to products such as cereal-grain products, fruit juices, and dairy products.

In selecting foods to consider as vehicles for fortification, the agency started with the basic principle that fortification of staple products that are commonly consumed in significant amounts by virtually all members of the target population is most likely to result in increased intakes of a specific nutrient by the target population (Ref. 26). The agency notes that, based on this general principle, cereal-grain products were the fortification vehicle recommended by the Food and Nutrition Board (Ref. 26).

Recent food consumption data confirm that 90 percent of women of childbearing age consume cereal-grain



products on a daily basis (Ref. 26). Therefore, all fortification options that the agency considered included fortification of cereal-grain products. Other commonly consumed food categories that may lend themselves to fortification with nutrient additives, including juices and dairy products, were also considered. Examples of dairy products and fruit juices that the agency considered for fortification included: Fluid cows' milk, reconstituted dry milk, condensed and evaporated milks, yogurts, and fruit juices such as orange, grapefruit, lemon, pineapple, apple, and grape.

FDA also included breakfast cereals in evaluating all fortification strategies because these products represent a traditional source of many nutrients, including folate, for those who consume them. Breakfast cereals are also consumed by many women of childbearing age (Ref. 27). Similarly, because approximately 30 to 40 percent of women of childbearing age use dietary supplements (Ref. 28), the agency also included the availability and continued use of dietary supplements in all fortification options.

In the agency's analyses of potential intakes from fortified foods, FDA applied different levels (70, 140, and 350 µg per 100 unit) of fortification to the broad range of food products under consideration, including certain dairy products and fruit juices.

When fortification at the lowest level, (i.e., 70 µg per unit) included fruit juices and dairy products in addition to cereal-grain products, intakes of high consumers exceeded the safe upper limit of 1 mg folate per day for most age groups. For example, fortification of cereal-grain products, fruit juices, and dairy products with 70 µg folic acid per unit, in addition to usual patterns of dietary supplement and breakfast cereal use, was estimated to result in daily folate intakes of high consumers in many groups in excess of 1 mg (58 FR 53254 at 53292, October 14, 1993).

On the other hand, as discussed more fully in the folate health claim proposal, FDA examined the effects of not including fruit juices and dairy products in its fortification model. As noted above, cereal-grain products are more widely consumed than dairy products or fruit juices by women of childbearing age. The agency examined the following fortification levels: 70, 140, or 350 µg folic acid per unit. If cereal-grain products were fortified with 70 µg folic acid per 100 g, folate intakes by adult population groups of "high consumers" would remain below 1 mg per day (58 FR 53254 at 53292, October 14, 1993). If fortification of cereal-grain products

was 140 µg per 100 g, intakes by adults 51+ years who were "high consumers" and who used supplements would approach but not exceed 1 mg folate per day. Fortification of cereal-grain products at 350 µg per 100 g could result in estimated daily intakes by "high consumers" among several sex/age groups in excess of 1 mg folate per day (58 FR 53254 at 53292, October 14, 1993).

As discussed above, FDA has concluded that 1 mg folate per day is the safe upper limit for folate intake. To ensure that the safe upper limit is not exceeded, FDA finds that folic acid fortification must be limited to the cereal-grain products that are the subject of a standard of identity that requires the addition of this substance at a level of 140 µg per 100 g. Fortification of other standardized foods with folic acid would cause the total daily folate intake of some segments of the population to exceed the safe daily intake of folate.

Because fruit juices and fruit juice replacements are not as widely consumed as cereal-grain products by women of childbearing age, they do not provide as effective a means for addressing the PHS recommendation that women of childbearing age consume 400 µg folic acid per day. Moreover, allowing their fortification in addition to the fortification of cereal-grain products would cause some members of the population to exceed the safe upper limit of intake. Therefore, FDA rejects the comments recommending that fruit juice replacements be permitted to add folic acid.

#### *F. Infant Formula*

One comment by a trade association representing infant formula manufacturers supported proposed § 172.345(e) which explicitly permits the addition of folic acid to infant formula, consistent with section 412(i) of the act (21 U.S.C. 350a(i)).

Another comment expressed concern that proposed § 172.345(e) would allow the addition of elevated levels of folic acid to infant formula.

FDA notes that in accordance with section 412(i) of the act, infant formulas are required to contain all essential nutrients, including folic acid. This rulemaking amends the food additive regulations to make clear that the use of folic acid in infant formula at a level necessary to provide 4 µg of folate is safe and meets the known nutrient requirements of infants when used at the required level. This level was set in accordance with the 1967 recommendations of the Committee on Nutrition of the American Academy of

Pediatrics (Ref. 29) and was incorporated into the 1980 Infant Formula Act and the 1986 Amendments to the act. Therefore, FDA concludes that addition of folic acid to infant formula at levels that comply with section 412 of the act is safe.

#### *G. Dietary Supplements*

In the proposal, FDA tentatively concluded that it should continue to provide for the use of folic acid in dietary supplements (58 FR 53312 at 53316, October 14, 1993). FDA received several comments supporting this tentative conclusion. Since publication of the proposal, however, the Dietary Supplement Health and Education Act of 1994 (DSHEA) was enacted. The DSHEA amended the act to exempt dietary ingredients, including vitamins, used in dietary supplements from the definition of a "food additive" (section 201(s)(6) of the act). Therefore, there is no need to provide for the use of folic acid in dietary supplements in the food additive regulations. Consequently, FDA has modified the proposed revision of § 172.345 by removing paragraph (f) and redesignating paragraph (g) as paragraph (f).

#### *H. Medical Foods*

A comment from a trade association that represents manufacturers of medical foods supported FDA's proposal to allow the addition of folic acid to medical foods.

FDA recognizes that it is necessary and appropriate to provide for the use of folic acid in foods that are formulated to be consumed or administered enterally under the supervision of a physician and that are intended for the specific dietary management of a disease condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation (medical foods). Therefore, FDA is providing for the use of folic acid in medical foods in § 172.345(f). In the proposal, FDA provided for medical foods as a subset of foods for special dietary use (see proposed § 172.345(g)). However, FDA has reevaluated this approach and concludes that it is more consistent with the act to provide for medical foods as a separate class of products (see section 403(r)(5)(A) of the act and compare section 411(c)(3) (21 U.S.C. 350(c)(3)) of the act with section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)).

FDA has provided for the addition of folic acid to foods for special dietary use in this final rule (§ 172.345(g)).

### *I. Meal-Replacements*

Several comments recommended that FDA allow the fortification of meal-replacement products with folic acid. These comments stated that weight control meal-replacement products should be allowed to be fortified with folic acid at a level based on the proportion of the total daily caloric intake that the product is intended to provide. One comment argued that meal-replacement products are unlikely to contribute to excess folic acid in the diet because their use is self-limiting. In addition, several comments argued that the addition of folic acid to meal-replacement products is consistent with the rationale used by FDA to justify the fortification of breakfast cereals, because meal-replacement products are alternatives to breakfast cereals, and like breakfast cereals, meal-replacement products are consumed typically as a single serving at the beginning of the day. In support of allowing addition of folic acid to meal-replacement products, one comment argued that these products are often consumed by women of childbearing age at breakfast in place of cereal, or they are eaten as a mid-morning snack when breakfast is skipped.

Another comment recommended that any meal-replacement products be permitted to contain up to 100 percent of the RDI per serving of folic acid. The comment argued that this level was justified because these products are usually promoted and knowingly purchased at a premium for their nutrient properties.

FDA recognizes that meal-replacement products intended to be consumed as the sole item of a meal or a diet provide persons consuming such products with essential nutrients. Moreover, folic acid fortification of such products provides an alternative to breakfast cereals and dietary supplements for women of child-bearing age that want to follow the PHS recommendation that they consume 400 µg of folic acid per day. Therefore, FDA concludes that meal-replacement products represented as a sole item of a meal or a diet may contain added folic acid.

To ensure that consumers of such meal-replacement products do not exceed the safe upper limit for folate per day, FDA has concluded that meal-replacement products that are intended to be consumed once per day may contain up to 400 µg folic acid per serving. However, to ensure that consumption of meal-replacement products does not result in folate intakes exceeding the safe upper limit of

1 mg folate per day, FDA has concluded that meal-replacement products intended to be consumed more than once per day may contain up to 200 µg folic acid per serving (§ 172.345(h)).

### *J. Foodstuff Premixes*

One comment requested that the agency clarify whether folic acid may be added to foodstuff premixes made with unenriched flour, but whose labeling indicates that the product contains enriched flour.

FDA recognizes that current manufacturing practices can involve the addition of nutrients, including folic acid, to premixes containing unenriched cereal-grain. FDA advises that the addition of folic acid to premixes made with unenriched cereal-grain flours, where a regulation establishing a standard of identity exists and where the standard specifically requires the addition of folic acid, is viewed by the agency as use in accordance with § 172.345(c).

### *K. Specifications*

Several comments requested that the proposed specifications for folic acid (§ 172.345(b)) be modified to include standards established by the United States Pharmacopeia (USP) for the use of folic acid in dietary supplements. These comments maintained that current USP and Food Chemicals Codex standards for folic acid are identical, and that including the USP requirements would help resolve any differences should USP improve the standards for folic acid. The comments noted that USP intends to establish new standards for folic acid.

As discussed previously, in response to the DSHEA, FDA has removed all references to the use of folic acid in dietary supplements from § 172.345. Establishing specifications for the use of folic acid in dietary supplements, as recommended in the comments, is beyond the scope of this rulemaking. Therefore, FDA concludes that new § 172.345(b) will specify FCC specifications for the food additive use of folic acid.

### *L. Analytical Methodology*

A comment noted that the current Association of Official Analytical Chemists (AOAC) method for folate quantitation in food is inadequate, and that there is a critical need for an improved method. Another comment noted that the current AOAC method is subject to considerable variability and requires 5 to 7 days to complete. The comment noted that this length of time is not practical for in-plant quality control purposes.

The agency recognizes that current methods for folate quantitation in foods may present a problem. FDA notes that folate is one of the most labile of the water-soluble vitamins, and the instability of the numerous folate forms in food has proven to be an obstacle to their quantitation.

Current methods to quantitate the level of folate in foods generally involve a two-step process consisting of extraction of folate from the food matrix followed by quantitation of folate levels. Extraction of folate from the food matrix is the most technically challenging step in the analysis. The AOAC has approved two methods for folate quantitation in food (Ref. 30). Both are microbiological assays. These assays can be completed within 72 hours after extraction of folate from the food sample.

Attempts to improve the extraction of folate from food matrices have focused on the use of a triple enzymatic digestion procedure using a broad specificity protease, an α-amylase, and chicken pancreatic conjugase. Use of the triple enzyme procedure has been found to increase measurable folate from a wide range of food matrices and has been shown to be particularly effective on cereal-grain based foods and milk and milk by-products. The triple enzyme procedure has been adapted into analysis protocols at FDA's Atlanta Center for Nutrient Analysis for the quantitation of folate in FDA's Total Diet samples (Ref. 31).

FDA scientists are studying the triple enzyme extraction procedure to identify foodstuffs for which the extraction method is most applicable. The agency also notes that a number of high pressure liquid chromatography (HPLC) methods for folate analysis and quantitation have been described in the literature. Because such HPLC methods are more rapid than the microbial methods currently in use, they offer the potential for development of a rapid folate quantitation assay for quality control purposes.

FDA will continue to work with AOAC to improve the methodology for quantitation of folate in food. The agency anticipates that the use of the triple enzyme extraction procedure and HPLC will result in advances over the current folate assays by reducing variability and assay time.

### *III. Environmental Impact*

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not

required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

#### IV. Objections

Any person who will be adversely affected by this regulation may at any time on or before April 4, 1996 file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

#### V. References

The following information has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday.

1. Department of Health and Human Services, Public Health Service, Recommendations for the Use of Folic Acid to Reduce the Number of Cases of Spina Bifida and Other Neural Tube Defects, *Morbidity and Mortality Weekly Report* 41/No. RR-14, pp. 1-7, September 11, 1992.
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#### List of Subjects in 21 CFR Part 172

Food additives, Incorporation by Reference, Reporting and recordkeeping requirements.

Therefore under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 172 is amended as follows:

**PART 172—FOOD ADDITIVES  
PERMITTED FOR DIRECT ADDITION  
TO FOOD FOR HUMAN  
CONSUMPTION**

1. The authority citation for 21 CFR 172 continues to read as follows:

Authority: Secs. 201, 401, 402, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 348, 371, 379e).

2. Section 172.345 is revised to read as follows:

**§ 172.345 Folic acid (folacin).**

Folic acid (CAS Reg. No. 59-30-3), also known as folacin or folate, may be safely used in food as a nutrient in accordance with the following prescribed conditions:

(a) Folic acid is the chemical *N*-[4-[[[(2-amino-1,4-dihydro-4-oxo-6-pteridiny)l)methyl]amino]benzoyl]-*L*-glutamic acid.

(b) Folic acid meets the specifications of the "Food Chemicals Codex," 3d ed. (1981), pp. 125 to 126, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) Folic acid may be added to foods subject to a standard of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act (the act) when the standard of identity specifically provides for the addition of folic acid.

(d) Folic acid may be added, at levels not to exceed 400 micrograms (µg) per serving, to breakfast cereals, as defined under § 170.3(n)(4) of this chapter.

(e) Folic acid may be added to infant formula in accordance with section 412(i)(1) of the act or with regulations issued under section 412(i)(2) of the act which are codified in § 107.100 of this chapter.

(f) Folic acid may be added to a medical food, as defined in section

5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)), at levels not to exceed the amount necessary to meet the distinctive nutritional requirements of the disease or condition for which the food is formulated.

(g) Folic acid may be added to food for special dietary use at levels not to exceed the amount necessary to meet the special dietary needs for which the food is formulated.

(h) Folic acid may be added to foods represented as meal-replacement products, in amounts not to exceed:

(1) Four hundred µg per serving if the food is a meal-replacement that is represented for use once per day; or

(2) Two hundred µg per serving if the food is a meal-replacement that is represented for use more than once per day.

Dated: February 28, 1996.

David A. Kessler,

*Commissioner of Food and Drugs.*

[FR Doc. 96-5012 Filed 2-29-96; 12:04 pm]

BILLING CODE 4160-01-P

Research in Education  
of Individuals  
With Disabilities  
Program; Notices

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Tuesday  
March 5, 1996

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**Part IV**

**Department of  
Education**

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**Research in Education of Individuals  
With Disabilities Program; Notices**

**DEPARTMENT OF EDUCATION****Research in Education of Individuals With Disabilities Program****AGENCY:** Department of Education.**ACTION:** Notice of final priority.

**SUMMARY:** The Secretary announces a final priority for the Research in Education of Individuals with Disabilities Program. The Secretary may use this priority in Fiscal Year 1996 and subsequent years. The Secretary takes this action to focus Federal assistance on identified needs to improve outcomes for children with disabilities. This final priority is intended to ensure wide and effective use of program funds.

**EFFECTIVE DATE:** This priority takes effect on April 4, 1996.

**FOR FURTHER INFORMATION CONTACT:**

Doris Andres, U.S. Department of Education, 600 Independence Avenue, S.W., Room 3526, Switzer Building, Washington, D.C. 20202-2641. Telephone: (202) 205-8125. Fax: (202) 205-8105. Individuals who use a telecommunications device for the deaf (TDD) may call the TDD number: (202) 205-8953. Internet: Doris—Andres@ed.gov

**SUPPLEMENTARY INFORMATION:** The Research in Education of Individuals with Disabilities Program, authorized by Part E of the Individuals with Disabilities Education Act (20 U.S.C. 1441-1443), provides support: to advance and improve the knowledge base and improve the practice of professionals, parents, and others providing early intervention, special education, and related services—including professionals in regular education environments—to provide children with disabilities effective instruction and enable these children to learn successfully.

On November 7, 1995, the Secretary published a notice of proposed priority for this program in the Federal Register (60 FR 56192-56193).

This final priority supports the National Education Goals by improving understanding of how to enable children and youth with disabilities to reach higher levels of academic achievement.

The publication of this priority does not preclude the Secretary from proposing additional priorities, nor does it limit the Secretary to funding only this priority, subject to meeting applicable rulemaking requirements. Funding of particular projects depends on the availability of funds, and the quality of the applications received. Further, FY 1996 priorities could be

affected by enactment of legislation reauthorizing these programs.

Note: This notice of final priority does not solicit applications. A notice inviting applications under this competition is published in a separate notice in this issue of the Federal Register.

**Analysis of Comments and Changes**

In response to the Secretary's invitation in the notice of proposed priority, four parties submitted comments. An analysis of the comments and of the changes in the proposed priority follows. Technical and other minor changes—as well as suggested changes the Secretary is not legally authorized to make under the applicable statutory authority—are not addressed.

**Priority—Initial Career Awards**

*Comment:* Two commenters expressed concern about limiting the priority to researchers in the initial phases of their careers. One commenter opposed limiting the competition to one category of researcher given the limited amount of funding, if any, that may be available over the next few years for research. The commenter felt strongly that the priority should focus on the highest quality of research that will continue to move the field forward, irrespective of the status of the careers of the researchers. The commenter also suggested that the priority be changed to encourage applications from persons with disabilities and from professionals who have demonstrated success in service delivery. Another commenter felt the priority could penalize those researchers who have spent a few years outside academia in the "real world" of service systems and programmatic realities, before they define research lines of interest for their research careers.

*Discussion:* The Department has a basic three pronged approach to develop the capacity of the special education research community. First, there is the Student-Initiated Research Projects priority (begun in 1974) that targets students at the post-secondary level to encourage students to pursue special education research. Second, the Initial Career Awards (ICA) competition (begun in 1990) is intended to bridge the gap between students and established researchers by providing support to individuals who are in the initial phases of their careers to initiate and develop promising lines of research. Third, the Field-Initiated Research Projects competition (begun in 1964 and the oldest continuous source of Federal funding in education) provides support to researchers who may be associated with institutions of higher education,

State and local educational agencies, and other public agencies and nonprofit private organizations. The Department believes this approach should be maintained because historically the students and beginning researchers have a difficult time competing against established researchers, and the Department believes it is important to encourage and support their participation to expand the special education research capacity into as broad a range as possible. The priority as written provides for the involvement of individuals with recognized professional expertise in the subject matter, and researchers with disabilities are encouraged to apply along with other eligible applicants.

The Secretary agrees with the commenter that researchers who have spent a few years outside academia are deserving of support, and they are eligible to apply to the Field-Initiated Research Projects competition.

Regarding the concern that there could be increasingly limited funding for research activities, the Secretary notes that final action on the 1996 appropriation is difficult to predict. Congress has not yet enacted a fiscal year 1996 appropriation for the Department of Education, and is considering proposals to eliminate or reduce funding in fiscal year 1996 for many of the discretionary grant programs administered by the Department for which the President requested funds. In order to ensure that the Department has the ability to award funds in the event they become available for programs for which funding is uncertain, the Department is proceeding with the publication of priorities and the conduct of planned competitions. The Department will make final decisions on the appropriate priorities and mix of awards for each program once a final appropriation is enacted.

*Changes:* None.

*Comment:* Two commenters suggested other areas that proposals should focus on including: (1) Natural settings for infants and young children; (2) inclusive classrooms; (3) the effective utilization of technology and telecommunications; (4) students with disabilities meeting educational standards established for all students; (5) integrating students with disabilities with their nondisabled peers throughout their educational experience; and (6) effective transition planning so that individuals with disabilities successfully participate in postsecondary education and are employed in integrated work settings.

**Discussion:** The Secretary concurs with the importance of the focus areas listed above.

However, the priority as written does not preclude proposals on the suggested topics. The Secretary prefers that applicants be given flexibility to propose their particular area of inquiry, and believes it would be overly prescriptive to limit potential applicants to certain topics.

**Changes:** None.

#### Priority

Under 34 CFR 75.105(c)(3) the Secretary gives an absolute preference to applications that meet the following priority. The Secretary will fund under this competition only applications that meet this absolute priority:

#### *Absolute Priority—Initial Career Awards*

**Background:** There is a need to enable individuals in the initial phases of their careers to initiate and develop promising lines of research that would improve early intervention services for infants and toddlers, and special education for children and youth with disabilities. Support for research activities among individuals in the initial phases of their careers is intended to develop the capacity of the special education research community. This priority would address the additional need to provide support for a broad range of field-initiated research projects—focusing on the special education and related services for children and youth with disabilities and early intervention for infants and toddlers—consistent with the purpose of the program as described in 34 CFR 324.1.

**Priority:** The Secretary establishes an absolute priority for the purpose of awarding grants to eligible applicants for the support of individuals in the initial phases of their careers to initiate and develop promising lines of research consistent with the purposes of the program. For purposes of this priority, the initial phase of an individual's career is considered to be the first three years after completing a doctoral program and graduating (e.g., for fiscal year 1996 awards, projects may support individuals who completed a doctoral program and graduated no earlier than the 1991–92 academic year).

Projects must—

(a) Pursue a line of inquiry that reflects a programmatic strand of research emanating either from theory or a conceptual framework. The line of research must be evidenced by a series of related questions that establish directions for designing future studies extending beyond the support of this

award. The project is not intended to represent all inquiry related to the particular theory or conceptual framework; rather, it is expected to initiate a new line or advance an existing one;

(b) Include, in its design and conduct, sustained involvement with nationally recognized experts having substantive or methodological knowledge and expertise relevant to the proposed research. Experts do not have to be at the same institution or agency at which the project is located, but the interaction must be sufficient to develop the capacity of the researcher to pursue effectively the research into mid-career activities. At least 50 percent of the researcher's time must be devoted to the project;

(c) Prepare its procedures, findings, and conclusions in a manner that informs other interested researchers and is useful for advancing professional practice or improving programs and services to infants, toddlers, children, and youth with disabilities and their families; and

(d) Disseminate project procedures, findings, and conclusions to appropriate research institutes and technical assistance providers.

A project's budget must include funds to attend the two-day Research Project Directors' meeting to be held in Washington, D.C. each year of the project.

**Applicable Program Regulations:** 34 CFR Part 324.

**Program Authority:** 20 U.S.C. 1441–1443.

(Catalog of Federal Domestic Assistance Number 84.023, Research in Education of Individuals with Disabilities Program)

Dated: February 28, 1996.

Katherine D. Seelman,

*Acting Assistant Secretary for Special Education and Rehabilitative Services.*

[FR Doc. 96–5056 Filed 3–4–96; 8:45 am]

BILLING CODE 4000–01–P

[CFDA No.: 84.023N]

#### **Research in Education of Individuals With Disabilities Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 1996**

**Purpose of Program:** To advance and improve the knowledge base and improve the practice of professionals, parents, and others providing early intervention, special education, and related services—including professionals in regular education environments—to provide children with disabilities effective instruction and enable them to successfully learn.

This notice supports the National Education Goals by improving understanding of how to enable children and youth with disabilities to reach higher levels of academic achievement.

**Eligible Applicants:** Eligible applicants are State and local educational agencies, institutions of higher education, and other public agencies and nonprofit private organizations.

**Applicable Regulations:** (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR Parts 74, 75, 77, 80, 81, 82, 85, and 86; (b) The regulations for this program in 34 CFR Part 324; and (c) The priority in the notice of final priority for this program, as published elsewhere in this issue of the Federal Register, applies to this competition.

**Note:** The regulations in 34 CFR Part 86 apply to institutions of higher education only.

**Deadline for Transmittal of Applications:** May 17, 1996.

**Applications Available:** March 15, 1996.

**Estimated Number of Awards:** 5.

**Project Period:** Up to 36 months.

**Available Funds:** In fiscal year 1996, the Department proposes to allocate approximately \$375,000 to support an estimated 5 projects, with a maximum size of award of \$75,000 for the first twelve months of the project. Multi-year projects will be level funded unless there are increases in costs attributable to significant changes in activity level.

The Congress has not yet enacted a fiscal year 1996 appropriation for the Department of Education. The Department is publishing this notice in order to give potential applicants adequate time to prepare applications. The estimate of the amount of funds that will be available for this competition is based in part on the President's 1996 budget request and in part on the level of funding available for fiscal year 1995.

Potential applicants should note, however, that the Congress is considering proposals to eliminate or to reduce funding in 1996 for many of the discretionary grant programs administered by the Department, including the program under which this competition would be conducted. Final action on the 1996 appropriation may require the Department to cancel the competition announced in this notice.

**Note:** The Department of Education is not bound by any estimates in this notice.

**For Applications and General Information Contact:** Requests for applications and general information should be addressed to: Claudette Carey,

U.S. Department of Education, 600 Independence Avenue, S.W., Switzer Building, Room 3525, Washington, D.C. 20202-2641. Telephone: (202) 205-9864. FAX: (202) 205-8105. Internet: Claudette—Carey@ed.gov  
Individuals who use a telecommunications device for the deaf (TDD) may call the TDD number: (202) 205-8953.

*For Technical Information Contact:*  
Doris Andres, U.S. Department of Education, 600 Independence Avenue, S.W., Room 3526, Switzer Building,

Washington, D.C. 20202-2641.  
Telephone: (202) 205-8125. FAX: (202) 205-8105. Internet: Doris—Andres@ed.gov

Information about the Department's funding opportunities, including copies of application notices for discretionary grant competitions, can be viewed on the Department's electronic bulletin board (ED Board), telephone (202) 260-9950; on the Internet Gopher Server at GOPHER.ED.GOV (under Announcements, Bulletins, and Press Releases); or on the World Wide Web at

<http://www.ed.gov/money.html>  
However, the official application notice for a discretionary grant competition is the notice published in the Federal Register.

Program Authority: 20 U.S.C. 1441-1443.

Dated: February 28, 1996.

Katherine D. Seelman,  
*Acting Assistant Secretary for Special Education and Rehabilitative Services.*  
[FR Doc. 96-5057 Filed 3-4-96; 8:45 am]

**BILLING CODE 4000-01-P**



Executive Order

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Tuesday  
March 5, 1996

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**Part V**

**Department of  
Housing and Urban  
Development**

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24 CFR Parts 962 and 984  
Family Self-Sufficiency Program;  
Streamlining Final Rule

**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT****24 CFR Parts 962 and 984**

[Docket No. FR-3989-F-01]

RIN 2577-AB61

**Office of the Assistant Secretary for Public and Indian Housing; Family Self-Sufficiency Program; Streamlining Final Rule**

**AGENCY:** Office of the Assistant Secretary for Public and Indian Housing, HUD.

**ACTION:** Final rule.

**SUMMARY:** This final rule amends HUD's regulations for the Family Self-Sufficiency (FSS) Program. In an effort to comply with the President's regulatory reform initiatives, this rule will streamline the Family Self-Sufficiency Program regulations by consolidating the public housing and the Section 8 FSS regulations and by eliminating redundant or otherwise unnecessary provisions. This final rule will make the Family Self-Sufficiency regulations clearer and more concise.

**EFFECTIVE DATE:** April 4, 1996.

**FOR FURTHER INFORMATION CONTACT:**

Louise K. Hunt, Director for Policies and Procedures, Room 4216, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone number (202) 708-3887, ext. 330. This number may be accessed through TDD by calling the Federal Relay Service at (202) 708-9300 or 1-800-877-TDDY (1-800-877-8389). (Other than the "1-800" number, these telephone numbers are not toll-free.)

**SUPPLEMENTARY INFORMATION:****Paperwork Reduction Act Statement**

This rule does not alter existing information collection requirements. The information collection requirements contained in §§ 962.201, 962.302, 962.305, and 962.401 of this rule were previously submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995 (42 U.S.C. 3501-3520) and had been approved under the control number 2577-0178. The Department's request for reinstatement of this control number is pending at OMB. (See notice published in the Federal Register on November 30, 1995, at 60 FR 61563.) An agency may not conduct or sponsor, and person is not required to respond to a collection of information unless the collection displays a valid control number. The OMB control number, when reinstated, will be added by separate notice in the Federal Register.

**Background**

On March 4, 1995, President Clinton issued a memorandum to all Federal departments and agencies regarding regulatory reinvention. In response to this memorandum, the Department of Housing and Urban Development conducted a page-by-page review of its regulations to determine which can be eliminated, consolidated, or otherwise improved. HUD has determined that the regulations for the public housing and Section 8 FSS Programs can be improved and streamlined by consolidating these regulations. The two current Code of Federal Regulations parts affected (part 962 for the public housing FSS Program and part 984 for the Section 8 FSS program) contain many identical provisions. Consolidating the parts should especially benefit HAs that operate both a public housing and a Section 8 FSS program.

Some provisions in the regulations are not regulatory requirements. For example, several sections in the regulations contain nonbinding guidance or explanations. While this information is very helpful to recipients, HUD will more appropriately provide this information through handbook guidance or other materials rather than maintain it in the CFR.

Section 984.201, Action Plan, contains revisions to conform to changes to administrative plan requirements in 24 CFR part 982 for the Section 8 Tenant-Based Assistance Program. (See 24 CFR 982.54, as added by 60 FR 34698, July 3, 1995, and the related preamble discussion of the FSS action plan at 60 FR 34661.) In conformity with those changes this rule removes the requirement in the current Section 8 FSS program regulation to include certain FSS policies in the administrative plan rather than in the action plan.

This rule does not affect the Indian housing FSS Program, which is codified at 24 CFR part 950 with other Indian housing programs. This rule applies to Indian Housing Authorities that opt or have opted to participate in the Section 8 FSS Program.

**Justification for Final Rulemaking**

HUD generally publishes a rule for public comment before issuing a rule for effect, in accordance with its own regulations on rulemaking in 24 CFR part 10. However, part 10 provides for exceptions to the general rule if the agency finds good cause to omit advance notice and public participation. The good cause requirement is satisfied when prior public procedure is

"impracticable, unnecessary, or contrary to the public interest" (24 CFR 10.1). HUD finds that good cause exists to publish this rule for effect without first soliciting public comment. This rule merely consolidates existing CFR parts and removes unnecessary regulatory provisions and does not establish or affect substantive policy. Therefore, prior public comment is unnecessary.

**Other Matters****Regulatory Flexibility Act**

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed and approved this final rule, and in so doing certifies that this rule will not have a significant economic impact on a substantial number of small entities. This rule merely streamlines regulations by removing redundant or unnecessary provisions. The rule will have no adverse or disproportionate economic impact on small businesses.

**Environmental Impact**

This rulemaking does not have an environmental impact. This rulemaking simply amends an existing regulation by consolidating and streamlining provisions and does not alter the environmental effect of the regulations being amended. A Finding of No Significant Impact with respect to the environment was made in accordance with HUD regulations in 24 CFR part 50 that implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332) at the time of development of regulations initially implementing the FSS Program (HUD Docket No. FR-2961). That finding remains applicable to this rule, and is available for public inspection between 7:30 a.m. and 5:30 p.m. weekdays in the Office of the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC.

**Executive Order 12612, Federalism**

The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, *Federalism*, has determined that this rule will not have substantial direct effects on States or their political subdivisions, or the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government. No programmatic or policy changes will result from this rule that would affect the relationship between the Federal Government and State and local governments.

*Executive Order 12606, The Family*

The General Counsel, as the Designated Official under Executive Order 12606, *The Family*, has determined that this rule will not have the potential for significant impact on family formation, maintenance, or general well-being, and thus is not subject to review under the Order. No significant change in existing HUD policies or programs will result from promulgation of this rule.

*Catalog*

The Catalog of Federal Domestic Assistance numbers for the programs affected by this proposed rule is 14.850, 14.855, and 14.887.

*List of Subjects**24 CFR Part 962*

Grant programs—housing and community development, Public housing, Reporting and recordkeeping requirements.

*24 CFR Part 984*

Grant programs—housing and community development, Housing, Rent subsidies, Reporting and recordkeeping requirements.

Accordingly, under the authority of 42 U.S.C. 3535(d), parts 962 and 984 of 24 Code of Federal Regulations are amended as follows:

**PART 962—[REMOVED]**

1. Part 962 is removed.
2. Part 984 is revised to read as follows:

**PART 984—SECTION 8 AND PUBLIC HOUSING FAMILY SELF-SUFFICIENCY PROGRAM****Subpart A—General**

Sec.

- 984.101 Purpose, scope, and applicability.
- 984.102 Program objectives.
- 984.103 Definitions.
- 984.104 Basic requirements of the FSS program.
- 984.105 Minimum program size.

**Subpart B—Program Development and Approval Procedures**

- 984.201 Action Plan.
- 984.202 Program Coordinating Committee (PCC).
- 984.203 FSS family selection procedures.
- 984.204 On-site facilities.

**Subpart C—Program Operation**

- 984.301 Program implementation.
- 984.302 Administrative fees.
- 984.303 Contract of participation.
- 984.304 Total tenant payment, family rent, and increases in family income.
- 984.305 FSS account.
- 984.306 Section 8 residency and portability requirements.

**Subpart D—Reporting**

984.401 Reporting.

Authority: 42 U.S.C. 1437f, 1437u, and 3535(d).

**Subpart A—General****§ 984.101 Purpose, scope, and applicability.**

(a) *Purpose.* (1) The purpose of the Family Self-Sufficiency (FSS) program is to promote the development of local strategies to coordinate the use of public and Indian housing assistance and housing assistance under the Section 8 rental certificate and rental voucher programs with public and private resources, to enable families eligible to receive assistance under these programs to achieve economic independence and self-sufficiency.

(2) The purpose of this part is to implement the policies and procedures applicable to operation of a local FSS program, as established under section 23 of the 1937 Act (42 U.S.C. 1437u), under HUD's rental voucher, rental certificate, and public housing programs.

(b) *Scope.* (1) Each PHA that received funding for public housing units under the FY 1991 and FY 1992 FSS incentive award competitions must operate a public housing FSS program.

(2) Each HA that received funding for Section 8 rental certificates or rental vouchers under the combined FY 1991/1992 FSS incentive award competition must operate a Section 8 FSS program.

(3) Unless the HA receives an exception from the program as provided in § 984.105, each HA that, in FY 1993 or any subsequent FY, received or receives funding for additional rental certificates or rental vouchers must operate a Section 8 FSS program or for additional public housing units must operate a public housing FSS program.

(c) *Applicability.*—(1) *Public housing.* This part applies to public housing assisted under the 1937 Act.

(2) *Indian Housing Authorities.* This part does not apply to Indian housing. The regulations governing Indian housing FSS programs are set forth in 24 CFR part 950, subpart R. The operation of a Section 8 FSS program is optional for Indian Housing Authorities (IHAs) that operate a certificate or voucher program. IHAs that elect to operate a Section 8 FSS program are subject to the requirements of this part, except that § 984.105(c) of this subpart A governing minimum program size does not apply to IHAs. Additionally, IHAs that received section 8 units under the FSS incentive award competitions and are operating a section 8 FSS program are

not subject to the minimum program size requirements.

(3) *Section 8.* This part also applies to the Section 8 rental certificate program and the Section 8 rental voucher program authorized by Section 8 of the 1937 Act and implemented at 24 CFR parts 882, 887, and 982.

**§ 984.102 Program objectives.**

The objective of the FSS program is to reduce the dependency of low-income families on welfare assistance and on Section 8, public or Indian housing assistance, or any Federal, State, or local rent or homeownership subsidies. Under the FSS program, low-income families are provided opportunities for education, job training, counseling, and other forms of social service assistance, while living in assisted housing, so that they may obtain the education, employment, and business and social skills necessary to achieve self-sufficiency, as defined in § 984.103 of this subpart A. The Department will measure the success of a local FSS program not only by the number of families who achieve self-sufficiency, but also by the number of FSS families who, as a result of participation in the program, have family members who obtain their first job, or who obtain higher paying jobs; no longer need benefits received under one or more welfare programs; obtain a high school diploma or higher education degree; or accomplish similar goals that will assist the family in obtaining economic independence.

**§ 984.103 Definitions.**

(a) The terms *1937 Act*, *Fair Market Rent*, *HUD*, *Indian Housing Authority (IHA)*, *Public Housing Agency (PHA)*, *Secretary*, and *Section 8*, as used in this part, are defined in 24 CFR 5.100.

(b) As used in this part:

*Certification* means a written assertion based on supporting evidence, provided by the FSS family or the HA, as may be required under this part, and which:

(1) Shall be maintained by the HA in the case of the family's certification, or by HUD in the case of the HA's certification;

(2) Shall be made available for inspection by HUD, the HA, and the public, as appropriate; and

(3) Shall be deemed to be accurate for purposes of this part, unless the Secretary or the HA, as applicable, determines otherwise after inspecting the evidence and providing due notice and opportunity for comment.

*Chief executive officer (CEO).* The CEO of a unit of general local government means the elected official or

the legally designated official, who has the primary responsibility for the conduct of that entity's governmental affairs. The CEO for an Indian tribe is the tribal governing official.

*Contract of participation* means a contract in a form approved by HUD, entered into between a participating family and an HA operating an FSS program that sets forth the terms and conditions governing participation in the FSS program. The contract of participation includes all individual training and services plans entered into between the HA and all members of the family who will participate in the FSS program, and which plans are attached to the contract of participation as exhibits. For additional detail, see § 984.303 of this subpart A.

*Earned income* means income or earnings included in annual income from wages, tips, salaries, other employee compensation, and self-employment. (See 24 CFR 813.106(b)(1), (2) and (8) and 913.106(b)(1), (2) and (8).) Earned income does not include any pension or annuity, transfer payments, any cash or in-kind benefits, or funds deposited in or accrued interest on the FSS escrow account established by an HA on behalf of a participating family.

*Effective date of contract of participation* means the first day of the month following the month in which the FSS family and the HA entered into the contract of participation.

*Eligible families* means:

(1) For the public housing FSS program, current residents of public housing. Eligible families also include current residents of public housing who are participants in local public housing self-sufficiency programs; and

(2) For Section 8 FSS program, current Section 8 rental certificate or rental voucher program participants, including participants in the Project Self-Sufficiency or Operation Bootstrap or other local self-sufficiency programs.

*Enrollment* means the date that the FSS family entered into the contract of participation with the HA.

*Family Self-Sufficiency program* or FSS program means the program established by an HA within its jurisdiction to promote self-sufficiency among participating families, including the provision of supportive services to these families, as authorized by section 23 of the 1937 Act.

*FSS account* means the FSS escrow account authorized by section 23 of the 1937 Act, and as provided by § 984.305 of this subpart A.

*FSS credit* means the amount credited by the HA to the participating family's FSS account.

*FSS family or participating family* means a family that resides in public housing or receives assistance under the rental certificate or rental voucher programs, and that elects to participate in the FSS program, and whose designated head of the family has signed the contract of participation.

*FSS related service program* means any program, publicly or privately sponsored, that offers the kinds of supportive services described in the definition of "supportive services" set forth in this § 984.103.

*FSS slots* refer to the total number of public housing units or the total number of rental certificates or rental vouchers that comprise the minimum size of an HA's respective public housing FSS program or Section 8 FSS program.

*FY* means Federal Fiscal Year (starting with October 1, and ending September 30, and designated by the calendar year in which it ends).

*HA* means a Housing Authority—either a Public Housing Agency (PHA) or an Indian Housing Authority (IHA).

*Head of FSS family* means the adult member of the FSS family who is the head of the household for purposes of determining income eligibility and rent.

*Housing subsidies* means assistance to meet the costs and expenses of temporary shelter, rental housing or homeownership, including rent, mortgage or utility payments.

*Individual training and services plan* means a written plan that is prepared for the head of the FSS family, and each adult member of the FSS family who elects to participate in the FSS program, by the HA in consultation with the family member, and which sets forth:

(1) The supportive services to be provided to the family member;

(2) The activities to be completed by that family member; and

(3) The agreed upon completion dates for the services and activities. Each individual training and services plan must be signed by the HA and the participating family member, and is attached to, and incorporated as part of the contract of participation. An individual training and services plan must be prepared for the head of the FSS family.

*JOBS Program* means the Job Opportunities and Basic Skills Training Program authorized under part F of title IV of the Social Security Act (42 U.S.C. 402(a)(19)).

*JTPA* means the Job Training Partnership Act (29 U.S.C. 1579(a)).

*Low-income family.* See definitions in 24 CFR 813.102 and 913.102.

*Participating family.* See definition for "FSS family" in this section.

*Program Coordinating Committee or PCC* is the committee described in § 984.202 of this part.

*Public housing* means housing assisted under the 1937 Act, excluding housing assisted under Section 8 of the 1937 Act.

*Self-sufficiency* means that an FSS family is no longer receiving Section 8, public or Indian housing assistance, or any Federal, State, or local rent or homeownership subsidies or welfare assistance. Achievement of self-sufficiency, although an FSS program objective, is not a condition for receipt of the FSS account funds. (See § 984.305 of this part.)

*Supportive services* means those appropriate services that an HA will make available, or cause to be made available to an FSS family under a contract of participation, and may include:

(1) *Child care*—child care of a type that provides sufficient hours of operation and serves an appropriate range of ages;

(2) *Transportation*—transportation necessary to enable a participating family to receive available services, or to commute to their places of employment;

(3) *Education*—remedial education; education for completion of secondary or post secondary schooling;

(4) *Employment*—job training, preparation, and counseling; job development and placement; and follow-up assistance after job placement and completion of the contract of participation;

(5) *Personal welfare*—substance/alcohol abuse treatment and counseling;

(6) *Household skills and management*—training in homemaking and parenting skills; household management; and money management;

(7) *Counseling*—counseling in the areas of:

(i) The responsibilities of homeownership;

(ii) Opportunities available for affordable rental and homeownership in the private housing market, including information on an individual's rights under the Fair Housing Act; and

(iii) Money management; and

(8) *Other services*—any other services and resources, including case management, reasonable accommodations for individuals with disabilities, that the HA may determine to be appropriate in assisting FSS families to achieve economic independence and self-sufficiency.

*Unit size or size of unit* refers to the number of bedrooms in a dwelling unit.

*Very low-income family.* See definitions in 24 CFR 813.102 and 913.102.

*Welfare assistance* means income assistance from Federal or State welfare programs, and includes assistance provided under the Aid to Families with Dependent Children (AFDC) Program, Supplemental Security Income (SSI) that is subject to an income eligibility test; Medicaid, food stamps, general assistance, or other assistance provided under a Federal or State program directed to meeting general living expenses, such as food, health care, child care, but does not include assistance solely directed to meeting housing expenses, and does not include transitional welfare assistance provided to JOBS participants.

#### **§ 984.104 Basic requirements of the FSS program.**

An FSS program established under this part shall be operated in conformity with:

(a) The regulations of this part, and for a Section 8 FSS program, the rental certificate and rental voucher regulations, codified in 24 CFR parts 882, 887, and 982 respectively, and for a public housing FSS program, the applicable public housing regulations, including the regulations in 24 CFR parts 913, 960, and 966;

(b) An Action Plan, as described in § 984.201, and provide comprehensive supportive services as defined in § 984.103; and

(c) An FSS program established under this part shall be operated in compliance with the nondiscrimination and equal opportunity requirements set forth in 24 CFR part 5, with the exception of Executive Orders 11246, 11625, 12432, and 12138.

#### **§ 984.105 Minimum program size.**

(a) *General.* Unless otherwise excepted from operation of an FSS program as provided in paragraph (c) of this section, or from operation of an FSS program of the minimum size as provided in paragraph (d) of this section, an HA shall operate an FSS program of the minimum size as determined in this section.

(1) *Determining minimum program size.* The minimum size of a FSS program:

(i) For a public housing FSS program, is equal to:

(A) The total number of public housing units reserved in FY 1993, and each subsequent FY; plus (if applicable)

(B) The number of public housing units reserved in FY 1991 and FY 1992 under the FSS incentive award competitions;

(ii) For a Section 8 FSS program, is equal to:

(A) The total number of rental certificates and rental vouchers reserved

in FY 1993, and each subsequent FY; plus (if applicable)

(B) The number of rental certificates and rental vouchers reserved under the combined FY 1991/1992 FSS incentive award competition.

(2) *Applicable units and certificates and vouchers.* In determining minimum program size, for a public housing FSS program, all new public housing rental units reserved will be counted and, for a Section 8 FSS program, all rental certificates and rental vouchers reserved will be counted, except those used to replace rental certificates or rental vouchers (renewals).

(b) *Maintaining minimum program size.* As the contracts of participation for FSS families are completed or terminated, replacement FSS families must be selected to maintain the minimum program size. A replacement family must be selected in accordance with the FSS family selection procedures set forth in § 984.203.

(c) *Exception to program operation.*

(1) Upon approval by HUD, an HA will not be required to establish and carry out a public housing or a Section 8 FSS program if the HA provides to HUD a certification, as defined in § 984.103, that the establishment and operation of such an FSS program is not feasible because of local circumstances, which may include, but are not limited to:

(i) Lack of accessible supportive services funding, including lack of the availability of programs under JTPA or JOBS;

(ii) Lack of funding for reasonable administrative costs;

(iii) Lack of cooperation by other units of State or local government; or

(iv) Lack of interest in participating in the FSS program on the part of eligible families.

(2) An exception will not be granted if HUD determines that local circumstances do not preclude the HA from effectively operating an FSS program that is smaller than the minimum program size.

(d) *Reduction in program size.* Upon approval by HUD, an HA may be permitted to operate a public housing or a Section 8 FSS program that is smaller than the minimum program size if the HA provides to HUD a certification, as defined in § 984.103, that the operation of an FSS program of the minimum program size is not feasible because of local circumstances, which may include, but are not limited to:

(1) Decrease in or lack of accessible supportive services, including decrease in the availability of programs under JTPA or JOBS;

(2) Decrease in or lack of funding for reasonable administrative costs;

(3) Decrease in or lack of cooperation by other units of State or local government;

(4) Decrease in or lack of interest in participating in the FSS program on the part of eligible families.

(e) *Review of certification records.*

HUD reserves the right to examine, during its management review of the HA, or at any time, the documentation and data that an HA relied on in certifying to the unfeasibility of its establishing and operating an FSS program, or of operating an FSS program of less than minimum program size.

### **Subpart B—Program Development and Approval Procedures**

#### **§ 984.201 Action Plan.**

(a) *Requirement for Action Plan—(1) General.* To participate in the FSS program, an HA must have a HUD-approved Action Plan that complies with the requirements of this section.

(2) [Reserved]

(b) *Development of Action Plan.* The Action Plan shall be developed by the HA in consultation with the chief executive officer of the applicable unit of general local government, and the Program Coordinating Committee.

(c) *Initial submission and revisions—(1) Initial submission.* Unless the dates set forth in this paragraph (c) are extended by HUD for good cause, an HA that is establishing its first FSS program must submit an Action Plan to HUD for approval within 90 days of notification by HUD of approval of:

(i) The HA's application for incentive award units; or

(ii) If the HA did not apply for FSS incentive award units, other funding that establishes the obligation to operate an FSS program.

(2) *Revision.* Following initial approval of the Action Plan by HUD, no further approval of the Action Plan is required unless the HA proposes to make policy changes to the Action Plan, or changes are required by HUD. Any changes to the Action Plan must be submitted to, and approved by, HUD.

(d) *Contents of Plan.* The Action Plan shall describe the policies and procedures of the HA for operation of a local FSS program, and shall contain, at a minimum, the following information:

(1) *Family demographics.* A description of the number, size, characteristics, and other demographics (including racial and ethnic data), and the supportive service needs of the families expected to participate in the FSS program;

(2) *Estimate of participating families.* A description of the number of eligible

FSS families who can reasonably be expected to receive supportive services under the FSS program, based on available and anticipated Federal, tribal, State, local, and private resources;

(3) *Eligible families from other self-sufficiency program.* If applicable, the number of families, by program type, who are participating in Operation Bootstrap, Project Self-Sufficiency, or any other local self-sufficiency program who are expected to agree to execute an FSS contract of participation.

(4) *FSS family selection procedures.* A statement indicating the procedures to be utilized to select families for participation in the FSS program, subject to the requirements governing the selection of FSS families, set forth in § 984.203. This statement must include a description of how the HA's selection procedures ensure that families will be selected without regard to race, color, religion, sex, handicap, familial status, or national origin.

(5) *Incentives to encourage participation—a description of the incentives that the HA intends to offer eligible families to encourage their participation in the FSS program (incentives plan).* The incentives plan shall provide for the establishment of the FSS account in accordance with the requirements set forth in § 984.305, and other incentives, if any, designed by the HA. The incentives plan shall be part of the Action Plan.

(6) *Outreach efforts.* A description of:

(i) The HA's efforts, including notification and outreach efforts, to recruit FSS participants from among eligible families; and

(ii) The HA's actions to be taken to assure that both minority and non-minority groups are informed about the FSS program, and how the HA will make this information known.

(7) *FSS activities and supportive services.* A description of the activities and supportive services to be provided by both public and private resources to FSS families, and identification of the public and private resources which are expected to provide the supportive services.

(8) *Method for identification of family support needs.* A description of how the FSS program will identify the needs and deliver the services and activities according to the needs of the FSS families;

(9) *Program termination; withholding of services; and available grievance procedures.* A description of the HA's policies concerning: terminating participation in the FSS program, withholding of supportive services, or terminating or withholding Section 8 assistance, on the basis of a family's

failure to comply with the requirements of the contract of participation; and the grievance and hearing procedures available for FSS families.

(10) *Assurances of non-interference with rights of non-participating families.* An assurance that a family's election not to participate in the FSS program will not affect the family's admission to public housing or to the Section 8 program or the family's right to occupancy in accordance with its lease.

(11) *Timetable for program implementation.* A timetable for implementation of the FSS program, as provided in § 984.301(a)(1), including the schedule for filling FSS slots with eligible FSS families, as provided in § 984.301;

(12) *Certification of coordination.* A certification that development of the services and activities under the FSS program has been coordinated with the JOBS Program; the programs provided under the JTPA; and any other relevant employment, child care, transportation, training, and education programs (e.g., Job Training for the Homeless Demonstration program) in the applicable area, and that implementation will continue to be coordinated, in order to avoid duplication of services and activities; and

(13) *Optional additional information.* Such other information that would help HUD determine the soundness of the HA's proposed FSS program.

(e) *Eligibility of a combined program.* An HA that wishes to operate a joint FSS program with other HAs may combine its resources with one or more HAs to deliver supportive services under a joint Action Plan that will provide for the establishment and operation of a combined FSS program that meets the requirements of this part.

(f) *Single action plan.* HAs implementing both a Section 8 FSS program and a public or Indian housing FSS program may submit one Action Plan.

#### **§ 984.202 Program Coordinating Committee (PCC).**

(a) *General.* Each participating HA must establish a PCC whose functions will be to assist the HA in securing commitments of public and private resources for the operation of the FSS program within the HA's jurisdiction, including assistance in developing the Action Plan and in implementing the program.

(b) *Membership—(1) Required membership.* The PCC must: (i) For a public housing FSS program, consist of representatives of the PHA, and the residents of public housing. The public

housing resident representatives shall be solicited from one or more of the following groups:

(A) An area-wide or city-wide resident council, if one exists;

(B) If the PHA will be transferring FSS participants to vacant units in a specific public housing development, the resident council or resident management corporation, if one exists, of the public housing development where the public housing FSS program is to be carried out;

(C) Any other public housing resident group, which the PHA believes is interested in the FSS program, and would contribute to the development and implementation of the FSS program; and

(ii) For a Section 8 FSS program, consist of representatives of the HA, and of residents assisted under the section 8 rental certificate or rental voucher program or under HUD's public or Indian housing programs.

(2) *Recommended membership.* Membership on the PCC also may include representatives of the unit of general local government served by the HA, local agencies (if any) responsible for carrying out JOBS training programs, or programs under the JTPA, and other organizations, such as other State, local or tribal welfare and employment agencies, public and private education or training institutions, child care providers, nonprofit service providers, private business, and any other public and private service providers with resources to assist the FSS program.

(c) *Alternative committee.* The HA may, in consultation with the chief executive officer of the unit of general local government served by the HA, utilize an existing entity as the PCC if the membership of the existing entity consists or will consist of the individuals identified in paragraph (b)(1) of this section, and also includes individuals from the same or similar organizations identified in paragraph (b)(2) of this section.

#### **§ 984.203 FSS family selection procedures.**

(a) *Preference in the FSS selection process.* An HA has the option of giving a selection preference for up to 50 percent of its public housing FSS slots and of its Section 8 FSS slots respectively to eligible families, as defined in § 984.103, who have one or more family members currently enrolled in an FSS related service program or on the waiting list for such a program. The HA may limit the selection preference given to participants in and applicants for FSS related service programs to one or more eligible FSS related service

programs. An HA that chooses to exercise the selection preference option must include the following information in its Action Plan:

(1) The percentage of FSS slots, not to exceed 50 percent of the total number of FSS slots for each of its FSS programs, for which it will give a selection preference;

(2) The FSS related service programs to which it will give a selection preference to the programs' participants and applicants; and

(3) The method of outreach to, and selection of, families with one or more members participating in the identified programs.

(b) *FSS selection without preference.* For those FSS slots for which the HA chooses not to exercise the selection preference provided in paragraph (a) of this section, the FSS slots must be filled with eligible families in accordance with an objective selection system, such as a lottery, the length of time living in subsidized housing, or the date the family expressed an interest in participating in the FSS program. The objective system to be used by the HA must be described in the HA's Action Plan.

(c) *Motivation as a selection factor—*  
(1) *General.* An HA may screen families for interest, and motivation to participate in the FSS program, provided that the factors utilized by the HA are those which solely measure the family's interest, and motivation to participate in the FSS program.

(2) *Permissible motivational screening factors.* Permitted motivational factors include requiring attendance at FSS orientation sessions or preselection interviews, and assigning certain tasks which indicate the family's willingness to undertake the obligations which may be imposed by the FSS contract of participation. However, any tasks assigned shall be those which may be readily accomplishable by the family, based on the family members' educational level, and disabilities, if any. Reasonable accommodations must be made for individuals with mobility, manual, sensory, speech impairments, mental or developmental disabilities.

(3) *Prohibited motivational screening factors.* Prohibited motivational screening factors include the family's educational level, educational or standardized motivational test results, previous job history or job performance, credit rating, marital status, number of children, or other factors, such as sensory or manual skills, and any factors which may result in discriminatory practices or treatment toward individuals with disabilities or minority or non-minority groups.

#### **§ 984.204 On-site facilities.**

Each HA may, subject to the approval of HUD, make available and utilize common areas or unoccupied dwelling units in public housing projects (or for IHAs, in Indian housing projects) to provide supportive services under an FSS program, including a Section 8 FSS program.

### **Subpart C—Program Operation**

#### **§ 984.301 Program implementation.**

(a) *Program implementation deadline—*(1) *Program start-up.* Except as provided in paragraph (a)(3) of this section, operation of a local FSS program must begin within 12 months of the earlier of notification to the HA of HUD's approval of the incentive award units or of other funding that establishes the obligation to operate an FSS program. Operation means that activities such as outreach, participant selection, and enrollment have begun. Full delivery of the supportive services to be provided to the total number of families required to be served under the program need not occur within 12 months, but must occur by the deadline set forth in paragraph (a)(2) of this section.

(2) *Full enrollment and delivery of service.* Except as provided in paragraph (a)(3) of this section, the HA must have completed enrollment of the total number of families required to be served under the FSS program (based on the minimum program size), and must have begun delivery of the supportive services within two years from the date of notification of approval of the application for new public housing units for a public housing FSS program or for new rental certificates or rental vouchers for a Section 8 FSS program.

(3) *Extension of program deadlines for good cause.* HUD may extend the deadline set forth in either paragraph (a)(1) or paragraph (a)(2) of this section if the HA requests an extension, and HUD determines that, despite best efforts on the part of the HA, the development of new public housing units will not occur within the deadlines set forth in this paragraph (a), the commitment by public or private resources to deliver supportive services has been withdrawn, the delivery of such services has been delayed, or other local circumstances warrant an extension of the deadlines set forth in this paragraph (a).

(b) *Program administration.* An HA may employ appropriate staff, including a service coordinator or program coordinator to administer its FSS program, and may contract with an appropriate organization to establish

and administer the FSS program, including the FSS account, as provided by § 984.305.

#### **§ 984.302 Administrative fees.**

(a) *Public housing FSS program.* The performance funding system (PFS), provided under section 9(a) of the 1937 Act, shall provide for the inclusion of reasonable and eligible administrative costs incurred by PHAs in carrying out the minimum program size of the public housing FSS programs. These costs are subject to appropriations by the Congress. However, a PHA may use other resources for this purpose.

(b) *Section 8 FSS program.* The administrative fees paid to HAs for HUD-approved costs associated with operation of an FSS program are established by the Congress and subject to appropriations.

#### **§ 984.303 Contract of participation.**

(a) *General.* Each family that is selected to participate in an FSS program must enter into a contract of participation with the HA that operates the FSS program in which the family will participate. The contract of participation shall be signed by the head of the FSS family.

(b) *Form and content of contract—*(1) *General.* The contract of participation, which incorporates the individual training and services plan(s), shall be in the form prescribed by HUD, and shall set forth the principal terms and conditions governing participation in the FSS program, including the rights and responsibilities of the FSS family and of the HA, the services to be provided to, and the activities to be completed by, the head of the FSS family and each adult member of the family who elects to participate in the program.

(2) *Interim goals.* The individual training and services plan, incorporated in the contract of participation, shall establish specific interim and final goals by which the HA, and the family, may measure the family's progress toward fulfilling its obligations under the contract of participation, and becoming self-sufficient. For each participating FSS family that is a recipient of welfare assistance, the HA must establish as an interim goal that the family become independent from welfare assistance and remain independent from welfare assistance at least one year before the expiration of the term of the contract of participation, including any extension thereof.

(3) *Compliance with lease terms.* The contract of participation shall provide that one of the obligations of the FSS family is to comply with the terms and

conditions of the respective public housing lease or Section 8-assisted lease.

(4) *Employment obligation*—(i) *Head of family's obligation.* The head of the FSS family shall be required under the contract of participation to seek and maintain suitable employment during the term of the contract and any extension thereof. Although other members of the FSS family may seek and maintain employment during the term of the contract, only the head of the FSS family is required to seek and maintain suitable employment.

(ii) *Seek employment.* The obligation to seek employment means that the head of the FSS family has applied for employment, attended job interviews, and has otherwise followed through on employment opportunities.

(iii) *Determination of suitable employment.* A determination of suitable employment shall be made by the HA based on the skills, education, and job training of the individual that has been designated the head of the FSS family, and based on the available job opportunities within the jurisdiction served by the HA.

(5) *Consequences of noncompliance with the contract.* The contract of participation shall specify that if the FSS family fails to comply, without good cause, with the terms and conditions of the contract of participation, which includes compliance with the public housing lease or the Section 8-assisted lease, the HA may:

- (i) Withhold the supportive services;
- (ii) Terminate the family's participation in the FSS program; or
- (iii) For the Section 8 FSS program, terminate or withhold the family's Section 8 assistance, except in the case where the only basis for noncompliance with the contract of participation is noncompliance with the lease, or failure to become independent from welfare assistance. However, failure to become independent from welfare assistance because of failure of the head of household to meet the employment obligation described in paragraph (a)(4) of this section, or failure of the FSS family to meet any other obligation under the contract of participation, except the interim goal concerning welfare assistance, is grounds for the HA to terminate or withhold Section 8 assistance.

(c) *Contract term.* The contract of participation shall provide that each FSS family will be required to fulfill those obligations to which the participating family has committed itself under the contract of participation

no later than 5 years after the effective date of the contract.

(d) *Contract extension.* The HA shall, in writing, extend the term of the contract of participation for a period not to exceed two years for any FSS family that requests, in writing, an extension of the contract, provided that the HA finds that good cause exists for granting the extension. The family's written request for an extension must include a description of the need for the extension. As used in this paragraph (d), "good cause" means circumstances beyond the control of the FSS family, as determined by the HA, such as a serious illness or involuntary loss of employment. Extension of the contract of participation will entitle the FSS family to continue to have amounts credited to the family's FSS account in accordance with § 984.304.

(e) *Unavailability of supportive services*—(1) *Good faith effort to replace unavailable services.* If a social service agency fails to deliver the supportive services pledged under an FSS family member's individual training and services plan, the HA shall make a good faith effort to obtain these services from another agency.

(2) *Assessment of necessity of services.* If the HA is unable to obtain the services from another agency, the HA shall reassess the family member's needs, and determine whether other available services would achieve the same purpose. If other available services would not achieve the same purpose, the HA shall determine whether the unavailable services are integral to the FSS family's advancement or progress toward self-sufficiency. If the unavailable services are:

(i) Determined not to be integral to the FSS family's advancement toward self-sufficiency, the HA shall revise the individual training and services plan to delete these services, and modify the contract of participation to remove any obligation on the part of the FSS family to accept the unavailable services, in accordance with paragraph (f) of this section; or

(ii) Determined to be integral to the FSS family's advancement toward self-sufficiency (which may be the case if the affected family member is the head of the FSS family), the HA shall declare the contract of participation null and void. Nullification of the contract of participation on the basis of unavailability of supportive services shall not be grounds for termination of Section 8 assistance.

(f) *Modification.* The HA and the FSS family may mutually agree to modify the contract of participation. The contract of participation may be

modified in writing with respect to the individual training and services plans, the contract term in accordance with paragraph (d) of this section, and designation of the head of the family.

(g) *Completion of the contract.* The contract of participation is considered to be completed, and a family's participation in the FSS program is considered to be concluded when one of the following occurs:

(1) The FSS family has fulfilled all of its obligations under the contract of participation on or before the expiration of the contract term, including any extension thereof; or

(2) 30 percent of the monthly adjusted income of the FSS family equals or exceeds the published existing housing fair market rent for the size of the unit for which the FSS family qualifies based on the HA's occupancy standards. The contract of participation will be considered completed and the family's participation in the FSS program concluded on this basis even though the contract term, including any extension thereof, has not expired, and the family members who have individual training and services plans have not completed all the activities set forth in their plans.

(h) *Termination of the contract.* The contract of participation is automatically terminated if the family's Section 8 assistance is terminated in accordance with HUD requirements. The contract of participation may be terminated before the expiration of the contract term, and any extension thereof, by:

- (1) Mutual consent of the parties;
- (2) The failure of the FSS family to meet its obligations under the contract of participation without good cause, including in the Section 8 FSS program the failure to comply with the contract requirements because the family has moved outside the jurisdiction of the HA;
- (3) The family's withdrawal from the FSS program;
- (4) Such other act as is deemed inconsistent with the purpose of the FSS program; or
- (5) Operation of law.

(i) *Option to terminate Section 8 housing and supportive service assistance.* The HA may terminate or withhold Section 8 housing assistance, the supportive services, and the FSS family's participation in the FSS program, if the HA determines, in accordance with the hearing procedures provided in 24 CFR 982.555 that the FSS family has failed to comply without good cause with the requirements of the contract of participation as provided in paragraph (b)(5) of this section.



(j) *Transitional supportive service assistance.* An HA may continue to offer to a former FSS family who has completed its contract of participation and whose head of family is employed, appropriate FSS supportive services in becoming self-sufficient (if the family still resides in public housing, or Section 8-assisted housing), or in remaining self-sufficient (if the family no longer resides in public, Section 8-assisted housing, or other assisted housing).

**§ 984.304 Total tenant payment, family rent, and increases in family income.**

(a)(1) *Public housing FSS program: Calculation of total tenant payment.* Total tenant payment for a family participating in the public housing FSS program is determined in accordance with the regulations set forth in 24 CFR part 913.

(2) *Section 8 FSS program: Calculation of family rent.* For the rental certificate program, total tenant payment for a family participating in the Section 8 FSS program and the amount of the housing assistance payment is determined in accordance with the regulations set forth in 24 CFR parts 813 and 882. For the rental voucher program, the housing assistance payment for a family participating in the FSS program is determined in accordance with the regulations set forth in 24 CFR part 887.

(b) *Increases in FSS family income.* Any increase in the earned income of an FSS family during its participation in an FSS program may not be considered as income or a resource for purposes of eligibility of the FSS family for other benefits, or amount of benefits payable to the FSS family, under any other program administered by HUD, unless the income of the FSS family equals or exceeds 80 percent of the median income of the area (as determined by HUD, with adjustments for smaller and larger families).

**§ 984.305 FSS account.**

(a) *Establishment of FSS account—(1) General.* The HA shall deposit the FSS account funds of all families participating in the HA's FSS program into a single depository account. The HA must deposit the FSS account funds in one or more of the HUD-approved investments.

(2) *Accounting for FSS account funds—(i) Accounting records.* The total of the combined FSS account funds will be supported in the HA accounting records by a subsidiary ledger showing the balance applicable to each FSS family. During the term of the contract of participation, the HA shall credit

periodically, but not less than annually, to each family's FSS account, the amount of the FSS credit determined in accordance with paragraph (b) of this section.

(ii) *Proration of investment income.* The investment income for funds in the FSS account will be prorated and credited to each family's FSS account based on the balance in each family's FSS account at the end of the period for which the investment income is credited.

(iii) *Reduction of amounts due by FSS family.* If the FSS family has not paid the family contribution towards rent, or other amounts, if any, due under the public housing or section 8-assisted lease, the balance in the family's FSS account shall be reduced by that amount (as reported by the owner to the HA in the Section 8 FSS program) before prorating the interest income. If the FSS family has fraudulently under-reported income, the amount credited to the FSS account will be based on the income amounts originally reported by the FSS family.

(3) *Reporting on FSS account.* Each HA will be required to make a report, at least once annually, to each FSS family on the status of the family's FSS account. At a minimum, the report will include:

(i) The balance at the beginning of the reporting period;

(ii) The amount of the family's rent payment that was credited to the FSS account, during the reporting period;

(iii) Any deductions made from the account for amounts due the HA before interest is distributed;

(iv) The amount of interest earned on the account during the year; and

(v) The total in the account at the end of the reporting period.

(b) *FSS credit—(1) Computation of amount.* For purposes of determining the FSS credit, "family rent" is: for the public housing program, the total tenant payment as defined in 24 CFR part 913; for the rental certificate program, the total tenant payment as defined in 24 CFR part 813; and for the rental voucher program, 30 percent of adjusted monthly income. The FSS credit shall be computed as follows:

(i) For FSS families who are very low-income families, the FSS credit shall be the amount which is the lesser of:

(A) Thirty percent of current monthly adjusted income less the family rent, which is obtained by disregarding any increases in earned income (as defined in § 984.103) from the effective date of the contract of participation; or

(B) The current family rent less the family rent at the time of the effective date of the contract of participation.

(ii) For FSS families who are low-income families but not very low-income families, the FSS credit shall be the amount determined according to paragraph (b)(1)(i) of this section, but which shall not exceed the amount computed for 50 percent of median income.

(2) *Ineligibility for FSS credit.* FSS families who are not low-income families shall not be entitled to any FSS credit.

(3) *Cessation of FSS credit.* The HA shall not make any additional credits to the FSS family's FSS account when the FSS family has completed the contract of participation, as defined in § 984.303(g), or when the contract of participation is terminated or otherwise nullified.

(c) *Disbursement of FSS account funds—(1) General.* The amount in an FSS account, in excess of any amount owed to the HA by the FSS family, as provided in paragraph (a)(3)(iii) of this section, shall be paid to the head of the FSS family when the contract of participation has been completed as provided in § 984.303(g), and if, at the time of contract completion, the head of the FSS family submits to the HA a certification, as defined in § 984.103, that, to the best of his or her knowledge and belief, no member of the FSS family is a recipient of welfare assistance.

(2) *Disbursement before expiration of contract term.* (i) If the HA determines that the FSS family has fulfilled its obligations under the contract of participation before the expiration of the contract term, and the head of the FSS family submits a certification that, to the best of his or her knowledge, no member of the FSS family is a recipient of welfare assistance, the amount in the family's FSS account, in excess of any amount owed to the HA by the FSS family, as provided in paragraph (a)(3)(iii) of this section, shall be paid to the head of the FSS family.

(ii) If the HA determines that the FSS family has fulfilled certain interim goals established in the contract of participation and needs a portion of the FSS account funds for purposes consistent with the contract of participation, such as completion of higher education (i.e., college, graduate school), or job training, or to meet start-up expenses involved in creation of a small business, the HA may, at the HA's sole option, disburse a portion of the funds from the family's FSS account to assist the family meet those expenses.

(3) *Verification of family certification.* Before disbursement of the FSS account funds to the family, the HA may verify that the FSS family is no longer a recipient of welfare assistance by

requesting copies of any documents which may indicate whether the family is receiving any welfare assistance, and contacting welfare agencies.

(d) *Succession to FSS account.* If the head of the FSS family ceases to reside with other family members in the public housing or the Section 8-assisted unit, the remaining members of the FSS family, after consultation with the HA, shall have the right to designate another family member to receive the funds in accordance with paragraph (c) (1) or (2) of this section.

(e) *Use of FSS account funds for homeownership.* A public housing FSS family may use its FSS account funds for the purchase of a home, including the purchase of a home under one of HUD's homeownership programs, or other Federal, State, or local homeownership programs unless such use is prohibited by the statute or regulations governing the particular homeownership program.

(f) *Forfeiture of FSS account funds—*(1) *Conditions for forfeiture.* Amounts in the FSS account shall be forfeited upon the occurrence of the following:

(i) The contract of participation is terminated, as provided in § 984.303(e) or § 984.303(h); or

(ii) The contract of participation is completed by the family, as provided in § 984.303(g), but the FSS family is receiving welfare assistance at the time of expiration of the term of the contract of participation, including any extension thereof.

(2) *Treatment of forfeited FSS account funds—*(i) *Public housing FSS program.* FSS account funds forfeited by the FSS family will be credited to the PHA's operating reserves and counted as other income in the calculation of the PFS operating subsidy eligibility for the next budget year.

(ii) *Section 8 FSS program.* FSS account funds forfeited by the FSS family will be treated as program receipts for payment of program expenses under the HA budget for the applicable Section 8 program, and shall be used in accordance with HUD requirements governing the use of program receipts.

#### **§ 984.306 Section 8 residency and portability requirements.**

(a) *Relocating FSS family.* For purposes of this section, the term "relocating FSS family" refers to an FSS

family that moves from the jurisdiction of an HA at least 12 months after signing its contract of participation.

(b) *Initial occupancy.* A family participating in the Section 8 FSS program must lease an assisted unit, for a minimum period of 12 months after the effective date of the contract of participation, in the jurisdiction of the HA which selected the family for the FSS program. Thereafter, the FSS family may move outside the jurisdiction of the initial HA consistent with the regulations of 24 CFR part 982.

(c) *Portability: relocation but continued participation in the FSS program of the initial HA—*(1) *General.*

A relocating FSS family may continue in the FSS program of the initial HA if the family demonstrates to the satisfaction of the initial HA that, notwithstanding the move, the relocating FSS family will be able to fulfill its responsibilities under the initial or modified contract of participation at its new place of residence. (For example, the FSS family may be able to commute to the supportive services specified in the contract of participation, or the family may move to obtain employment as specified in the contract.)

(2) *Single contract of participation.* If the relocating family remains in the FSS program of the initial HA, there will only be one contract of participation, which shall be the contract executed by the initial HA.

(d) *Portability: relocation and participation in the FSS program of the receiving HA—*(1) *General.* A relocating FSS family may participate in the FSS program of the receiving HA, if the receiving HA allows the family to participate in its program. An HA is not obligated to enroll a relocating FSS family in its FSS program.

(2) *Two contracts of participation.* If the receiving HA allows the relocating FSS family to participate in its FSS program, the receiving HA will enter into a new contract of participation with the FSS family for the term on the remaining contract with the initial HA. The initial HA will terminate its contract of participation with the family.

(e) *Single FSS account.* Regardless of whether the relocating FSS family remains in the FSS program of the initial HA or is enrolled in the FSS program of the receiving HA, there will

be a single FSS account which will be maintained by the initial HA. When an FSS family will be absorbed by the receiving HA, the initial HA will transfer the family's FSS account to the receiving HA.

(f) *FSS program termination; loss of FSS account; and termination of Section 8 assistance.* (1) If an FSS family that relocates to another jurisdiction, as provided under this section, is unable to fulfill its obligations under the contract of participation, or any modifications thereto, the HA, which is party to the contract of participation, may:

(i) Terminate the FSS family from the FSS program and the family's FSS account will be forfeited; and

(ii) Terminate the FSS family's Section 8 assistance on the ground that the family failed to meet its obligations under the contract of participation.

(2) In the event of forfeiture of the family's FSS account, the funds in the family's FSS account will revert to the HA maintaining the FSS account for the family.

#### **Subpart D—Reporting**

##### **§ 984.401 Reporting.**

Each HA that carries out an FSS program under this part shall submit to HUD, in the form prescribed by HUD, a report regarding its FSS program. The report shall include the following information:

(a) A description of the activities carried out under the program;

(b) A description of the effectiveness of the program in assisting families to achieve economic independence and self-sufficiency;

(c) A description of the effectiveness of the program in coordinating resources of communities to assist families to achieve economic independence and self-sufficiency; and

(d) Any recommendations by the HA or the appropriate local program coordinating committee for legislative or administrative action that would improve the FSS program and ensure the effectiveness of the program.

Dated: February 26, 1996.

Kevin E. Marchman,  
Acting Assistant Secretary for Public and Indian Housing.

[FR Doc. 96-4908 Filed 3-4-96; 8:45 am]

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Estimated  
Federal  
Funding

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Tuesday  
March 5, 1996

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**Part VI**

**Department of  
Housing and Urban  
Development**

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**NOFA for Emergency Shelter Grants Set-  
Aside for Indian Tribes and Alaskan  
Native Villages; Notice**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

### Office of the Assistant Secretary for Public and Indian Housing

[Docket No. FR-4002-N-01]

### NOFA for Emergency Shelter Grants Set-Aside for Indian Tribes and Alaskan Native Villages

**AGENCY:** Office of the Assistant Secretary for Public and Indian Housing, HUD.

**ACTION:** Notice of funding availability.

**SUMMARY:** This NOFA announces the availability of approximately \$1,150,000 in funds for emergency shelter grants to be allocated to Indian tribes and Alaskan Native villages by competition for Fiscal Year (FY) 1996. Assistance provided to Indian tribes and Alaskan Native villages under this NOFA will be used to help improve the quality of existing emergency shelters for the homeless, to make available additional emergency shelters, to meet the costs of operating emergency shelters and of providing essential social services to homeless individuals, and to help prevent homelessness. This ESG set-aside allocation will increase the availability and expedite receipt of program funds to Native American communities. This NOFA contains: (1) Information concerning eligible applicants, (2) Information on funding available within each HUD Indian program region, (3) Information on application requirements and procedures, and (4) A description of applicable statutory changes to the ESG program.

Note: The Congress has not yet enacted an FY 1996 appropriation for HUD. However, HUD is publishing this notice in order to give potential applicants adequate time to prepare applications. The amount of funds announced in this NOFA is an estimate of the amount likely to be enacted in 1996. HUD is not bound by the estimate set forth in this notice. The estimated amount may be adjusted based on the enacted 1996 appropriation.

**DATES:** Applications must be received by the appropriate HUD Office of Native American Programs (ONAP) by no later than 3:00 p.m. local time (i.e., the time in the office to which the application is submitted) on April 19, 1996.

**ADDRESSES:** Application packages are available from the HUD Offices of Native American Programs (ONAPs) listed in Appendix 2 to this NOFA. The Office of Native American Programs (ONAP) serving the area in which the applicant's project is located must receive an original application and one

copy by the deadline described in the "Dates" section of this NOFA.

**FOR FURTHER INFORMATION CONTACT:** Applicants may contact the appropriate Office of Native American Programs (ONAPs) for further information. Appendix 2 to this NOFA contains a complete list of these offices with their addresses and telephone numbers.

#### SUPPLEMENTARY INFORMATION:

##### Paperwork Reduction Act Statement

The information collection requirements contained in this Notice of Funding Availability (NOFA) have been approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act (44 U.S.C. 3501-3520), and assigned OMB control number 2577-0205. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a valid control number.

#### I. Purpose and Substantive Description

##### A. Authority and Purpose

The Emergency Shelter Grants (ESG) program was first established in section 101(g) of Public Law 99-500 (approved October 18, 1986), making appropriations for Fiscal Year (FY) 1987 as provided in H.R. 5313. The program was reauthorized with amendments in the Stewart B. McKinney Homeless Assistance Act, as amended (42 U.S.C. 11371-11378) (McKinney Act). Section 832(f) of the National Affordable Housing Act (NAHA) (Pub. L. 101-625, approved November 28, 1990) provided for the explicit eligibility of Indian tribes for ESG program assistance, and established a set-aside allocation for Indian tribes that is equal to 1 percent of the amounts appropriated for the ESG program. Regulations governing the ESG program are in 24 CFR part 576, except as superseded by statutory amendments under NAHA and the Housing and Community Development Act of 1992 (1992 Act) (Pub. L. 102-550, approved October 28, 1992), as discussed below.

Approximately \$1,150,000 is available for the Indian Emergency Shelter Grants (ESG) Program as authorized by subtitle B, title IV of the Stewart B. McKinney Homeless Assistance Act, as amended. The proposed rule on Emergency Shelter Grants Program; Set-Aside Allocation for Indian Tribes and Alaskan Native Villages, published in the Federal Register on April 5, 1993 (58 FR 17764), describes the method for allocating these funds.

Note: The Congress has not yet enacted an FY 1996 appropriation for HUD. However, HUD is publishing this notice in order to give potential applicants adequate time to prepare

applications. The amount of funds announced in this NOFA is an estimate of the amount likely to be enacted in 1996. HUD is not bound by the estimate set forth in this notice. The estimated amount may be adjusted based on the enacted 1996 appropriation.

These grants will be governed by all provisions applicable to the ESG program, including the provisions in the Housing and Community Development Act of 1992 that became effective upon that law's enactment, such as the authorization to make eligible the use of grant funds for staff costs relating to the operation of emergency shelters up to a maximum amount of 10 percent of the grant, and the requirement that the recipient establish a "formal process" in order to terminate assistance under the program.

Assistance provided to Indian tribes and Alaskan Native villages under this NOFA will be used to help improve the quality of existing emergency shelters for the homeless, make available additional emergency shelters, meet the costs of operating emergency shelters and of providing essential social services to homeless individuals, and help prevent homelessness. This ESG set-aside allocation will increase the availability and expedite receipt of program funds to Native American communities.

##### B. Statutory Amendments

This NOFA addresses section 832 of NAHA, which contains numerous amendments to the McKinney Act, and several amendments to the ESG program in the 1992 Act. These statutory amendments supersede applicable provisions of the program regulations found in 24 CFR part 576. This NOFA describes these statutory changes to assist Indian tribes in complying with program requirements, including the NAHA and 1992 Act amendments (see Appendix 1 of this NOFA for a listing of statutory amendments that apply to this program).

#### II. Application Process

##### A. Allocation Amounts

This NOFA announces the availability of approximately \$1,150,000 in funding for FY 1996 to fund competitive grants to Indian tribes for emergency shelter grants. Set-aside allocations of the total amount to each area Office of Native American Programs (ONAP) are detailed in the following chart:

# ALLOCATION OF ESG SET-ASIDE FOR INDIAN TRIBES BY HUD AREA ONAPS FOR FY 1996

	Percent
Eastern/Woodlands .....	16.70
Southern Plains .....	19.75
Northern Plains .....	18.92
Southwest .....	26.70
Northwest .....	8.60
Alaska .....	9.33
Total .....	100.00

HUD reserves the right to negotiate reductions in the amounts requested by applicants based on the overall demand for the funds. HUD further reserves the right to reallocate these amounts as provided in section II.F, Ranking and Selection, of this NOFA. Each Indian tribe must spend all of the grant amounts it is awarded within 24 months of the date of the grant award by HUD. Any emergency shelter grant amounts that are not spent within this time period may be recaptured and added to the following fiscal year's ESG set-aside for Indian tribes.

## B. Eligibility and Threshold Requirements

### (1) Eligible Applicants

Eligible applicants are any Indian Tribe, band, group, or nation, including Alaskan Indians, Aleuts, and Eskimos, and any Alaskan native village of the United States which is considered an eligible recipient under Title I of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450), or which had been an eligible recipient under the State and Local Fiscal Assistance Act of 1972 (31 U.S.C. 1221). Eligible recipients under the State and Local Fiscal Assistance Act of 1972 are those that have been determined eligible by the Department of the Treasury, Office of Revenue Sharing.

Tribal organizations which are eligible under title I of the Indian Self-Determination and Education Assistance Act may apply on behalf of any Indian Tribe, band, group, nation, or Alaskan native village eligible under that act for funds under this part when one or more of these entities have authorized the Tribal organization to do so through concurring resolutions. Such resolutions must accompany the application for funding. Eligible Tribal organizations under title I of the Indian Self-Determination and Education Assistance Act will be determined by the Bureau of Indian Affairs.

Only eligible applicants shall receive grants. However, eligible applicants may

contract or otherwise agree with noneligible entities such as States, cities, counties, or other organizations to assist in the preparation of applications and to help implement assisted activities. For instance, private nonprofit organizations are not eligible to apply directly to HUD for a grant, but may receive funding from a grantee if the grantee determines that the nonprofit has the financial and organizational capacity to carry out the proposed activities.

### (2) Thresholds

The selection process for the Indian tribe set-aside program includes a preliminary threshold review. The applicant must clearly demonstrate and HUD will review each application to determine whether:

- The application is adequate in form, time, and completeness;
- The applicant is eligible; and
- The proposed activities and persons to be served are eligible for assistance under the program.

### C. Obtaining Applications

Application packages are available from the HUD area Offices of Native American Programs listed in Appendix 2 to this NOFA.

### D. Submitting Applications

The ONAP serving the area in which the applicant's project is located must receive an original application and one copy no later than 3:00 p.m. local time (i.e., the time in the office to which the application is submitted) on the deadline date April 19, 1996. Applications transmitted by FAX will not be accepted. A determination that an application was received on time will be made solely on receipt of the original application at the appropriate Office of Native American Programs serving the applicant's project.

The deadline is firm as to date and hour. In the interest of fairness to all competing applicants, HUD will treat any application that is received after the deadline as ineligible for consideration. Applicants should take this practice into account and make early submission of their materials to avoid any risk of ineligibility brought about by unanticipated delays or other delivery-related problems.

### E. Rating Criteria

Applications that fulfill each of the threshold review requirements described in Section II.B, Eligibility and Threshold Requirements, of this NOFA will be rated up to 100 points based on the following criteria.

(1) *Applicant capacity (30 points)*. HUD will award up to 30 points to an applicant that demonstrates the ability to carry out activities under its proposed program within a reasonable time, and in a successful manner, after execution of the grant agreement by HUD. Reviewers' knowledge of the applicant's previous experience will weigh heavily in the scoring. Documented evidence of poor or slow performance will enter strongly into that determination. The applicants that rate highest on this criterion will show substantial experience as an organization and/or staff in past endeavors that are directly related to the proposed project.

The applicant will receive the following points if it:

- Shows *substantial* experience as an organization and/or staff in past endeavors that are *directly and comprehensively* related to the proposed projects; and demonstrates *assurance* of assisting the homeless within a reasonable time.
- Shows *substantial* experience as an organization and/or staff in past endeavors that are *closely* (but not directly or comprehensively) related to the proposed project; and shows *promise* of assisting the homeless within a reasonable time.
- Shows *limited* experience as an organization and/or staff in past endeavors that are *closely* (but not directly or comprehensively) related to the proposed project; and shows *promise* of assisting the homeless within a reasonable time.
- Shows *limited* experience as an organization and/or staff in past endeavors that are only *remotely* related to the proposed project; or some evidence exists that brings into question the organization's capacity to implement the proposed project; and it is *unclear* whether the organization will be able to assist the homeless within a reasonable time.
- Shows *no* evidence as an organization and/or staff in past endeavors that relate to the demands of the proposed project; and substantial evidence exists that the organization is *incapable* of implementing the proposed project; and documented evidence exists that the organization *will not be able* to assist the homeless within a reasonable time.

(2) *Need (20 points)*. HUD will award up to 20 points to an applicant that demonstrates the existence of an unmet need for the proposed project in the area to be served. The applicants that rate

highest on this criterion will: (a) clearly define the unmet housing and essential services needs of the homeless population proposed to be served in the area to be served by the project, (b) demonstrate in-depth knowledge of the population to be served and its needs, and (c) set forth an outreach strategy that assures that the intended population will be served.

The applicant will receive the following points if it:

- 20 *Clearly* defines the unmet housing and supportive services needs of the homeless population(s) to be served *in the area to be served* by the project. That unmet need (as described) is *great* relative to other applications reviewed. Presents evidence of use of *credible* surveys or other data gathering mechanisms to support claims made. Application reveals *in-depth* understanding of the population(s) to be served and of its unmet housing and supportive services needs. Entry and outreach policies will *ensure* that the population(s) proposed to be served will *actually* be served by the project.
- 15 *Generally* defines the unmet housing and supportive services needs of a homeless population(s) to be served, but not as is comparable in magnitude to most other applications reviewed. Presents evidence of use of *acceptable* surveys or other data gathering mechanisms to support claims made. Application reveals *in-depth* understanding of the population(s) to be served and of its unmet housing and supportive services needs. Entry and outreach policies will *ensure* that the population(s) proposed to be served will *actually* be served by the project.
- 10 *Generally* defines the unmet housing and supportive service needs of a homeless population(s) to be served, but not as clearly in the specific area to be served. That unmet need (as described) is comparable in magnitude to most other applications reviewed. Presents evidence of use of *acceptable* surveys or other data gathering mechanisms to support claims made. Application reveals *general* understanding of the population(s) to be served and of its unmet housing and supportive services needs. Entry and outreach policies will *likely ensure* that the population(s) proposed to be served will *actually* be served.
- 5 Offers a *fragmentary description* of the unmet housing and supportive

services needs of the homeless population(s) to be served by the project with *minimal evidence supporting the claim*. That unmet need (as described) is less in magnitude than most other applications reviewed. Supportive documentation is *very limited or tangential* to the unmet needs described. Application reveals only *limited* understanding of the population(s) proposed to be served or of its unmet needs. Entry and outreach policies relate *only indirectly* to the population(s) that the applicant proposes to serve.

- 0 *Fails to delineate* the unmet housing and supportive services needs of the homeless population(s) to be served by the project. Application reveals a *complete absence of understanding* of the population(s) to be served or of its unmet housing and supportive services needs.

(3) *Service to homeless population (20 points)*. HUD will award up to 20 points to an applicant that proposes to serve that part of the Indian homeless population that is most difficult to reach and serve, i.e., those persons having a primary nighttime residence that is a public or private place not designed for, or ordinarily used as, sleeping accommodations for human beings. In urban areas, this is usually referred to as living "on the street." To the extent that Indians living on reservations live in such situations (e.g., sleeping in cars, abandoned structures, out in the open), they meet the definition of living in conditions similar to living on the street.

HUD will focus upon proposed outreach and intake plans, and especially the degree to which such plans would maximize the likelihood that homeless persons would be served by the proposed project. The outreach strategy/intake procedures to seek out and evaluate the needs of the population to be served should be clearly described in the application.

The applicant will receive the following points if it:

- 20 *Clearly* specifies the reasons that individuals will be hard to reach in terms of their geographic location, specific problems, or their willingness to enter into the program; and states *clearly* how outreach to these individuals will be achieved by the applicant or with other organizations; and *specifically* reveals how intake process will be used to identify the needs of the population to be served.

- 10 States only that individuals will be hard to reach and does not contain any description of their geographic location, specific problems, or their willingness to enter into the program; and does not describe what outreach process will be used to seek out those individuals by the applicant or with other organizations; and states that an intake process will be used to identify the needs of the population to be served.

- 5 States only that individuals will be hard to reach and does not contain any description of their geographic location, specific problems, or their willingness to enter into the program; and does not describe what outreach process will be used to seek out those individuals by the applicant or with other organizations; and contains *little information* about what intake process will be used to identify the needs of the population to be served.

- 0 *Fails to delineate* that the population is hard to reach or what outreach measures will be used to contact the population to be served by the project.

(4) *Appropriateness of essential services (30 points)*. HUD will award up to 30 points to an applicant that proposes essential services that: (a) are appropriate to the needs of the population proposed to be served; (b) are used or coordinated with existing sources of supportive services and networks of support in the community; and (c) to the degree possible, help to move residents to longer term housing situations. Applicants should describe what services are available and how they will make those services accessible to the people they serve. In addition, HUD will evaluate the means by which the people to be served will be assisted in moving to permanent housing that is appropriate and affordable. Applicants should describe what resources are available to assist the population they serve to find permanent housing.

The applicant will receive the following points if it:

- 30 Proposes a program of essential services that is *comprehensive* and that gives promise of being of very high quality; and that is *generally appropriate* to the needs of the population proposed to be served, responds to the changing needs of that population(s), *offers a personalized response* to the individual needs of the residents served; and *coordinates extensively* with other sources, public and

private, of essential services and networks of support already existing within the community; and can demonstrate with reasonable certainty that the results of the program are likely to be successful. The applicant will have access to housing counseling, assistance with applying for other Federal, State, or local housing assistance programs, referrals to other organizations involved in these activities, or other assistance such as moving assistance, security deposits, or landlord/tenant negotiation directly related to entering transitional or permanent adequate and affordable housing.

- 20 Proposes a program of essential services that is *reasonably comprehensive* and that gives promise of being of good quality; that responds to a genuine need, as identified in Element (3); proposes use of other sources of essential services and existing networks of support; and offers *reasonable assurance* that the results of the program are likely to be successful. The applicant will have access to housing counseling, assistance with applying for other Federal, State, or local housing assistance programs, referrals to other organizations involved in these activities, or other assistance such as moving assistance, security deposits, or landlord/tenant negotiation directly related to entering transitional or permanent adequate and affordable housing.
- 10 Proposes a program of essential services that is *reasonably comprehensive* and that gives promise of being of good quality; that responds to a genuine need, as identified in Element (3); proposes use of other sources of essential services and existing networks of support; and offers *reasonable assurance* that the results of the program are likely to be successful. The applicant will have access to housing counseling, assistance with applying for other Federal, State, or local housing assistance programs, or be able to make referrals to other organizations involved in these activities.
- 5 Presents a proposed project with a few services that meet basic needs but are *not designed* to encourage residents to move to greater independence within an emergency shelter environment.
- 0 Presents a proposed project with *no essential services* or with *services that are clearly inappropriate* to the population to be served; success is

*highly unlikely*. The application fails to indicate how or when residents will be able to leave emergency shelter for transitional or permanent housing.

#### F. Ranking and Selection

Applications from Indian tribes within the area served by the applicable HUD Office of Native American Programs will be assigned a rating score and placed in ranked order, based upon the rating criteria listed in Section II.E of this NOFA. Only those applications receiving at least 50 total points will be given funding consideration. In the final stage of the selection process, qualified applicants will be selected for funding in accordance with their ranked order within each area ONAP, to the extent that funds are available within that area ONAP's jurisdiction.

In the event of a tie between applicants, the applicant with the highest total points for rating criterion (2), Need, in section II.E of this NOFA, will be selected. In the event of a procedural error that, when corrected, would warrant selection of an otherwise eligible applicant under this NOFA, HUD may select that applicant when sufficient funds become available.

Depending on the availability of funds, HUD may fund qualified applications regardless of location. If an area ONAP has insufficient funds to make awards to all of its qualified applicants, HUD may reallocate funds to that office from any other area ONAP that has funds remaining after making awards to all of its qualified applications.

#### III. Checklist for Application Submission Requirements

A checklist of submission requirements is provided at Appendix 3 to this NOFA, to assist the applicant in preparing a complete application.

#### IV. Corrections To Deficient Applications

HUD will notify the applicant if there are any curable technical deficiencies in the application. Curable technical deficiencies relate to minimum eligibility requirements (such as certifications and signatures) that are necessary for funding approval but that do not relate to the quality of the applicant's program proposal under the selection criteria. The applicant must submit corrections in accordance with the information provided by HUD within 14 calendar days of the date of the HUD notification.

In accordance with the provisions of 24 CFR part 4, subpart B, HUD may contact an applicant to seek clarification

of an item in an applicant's application, or to request additional or missing information. The clarification or the request for additional or missing information shall not relate to items that would improve the substantive quality of the application pertinent to the funding decision.

#### V. Other Matters

##### A. Environmental Impact

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969. This Finding is available for public inspection between 7:30 a.m. to 5:30 p.m. weekdays in the Office of the Rules Docket Clerk in the Office of the General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410-0500.

##### B. Federalism Impact

The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, Federalism, has determined that the policies contained in this NOFA will not have substantial direct effects on States or their political subdivisions, or the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government. As a result, this NOFA is not subject to review under the Order. This NOFA announces the availability of funds set aside for Indian tribes for emergency shelter activities and invites applications from eligible applicants.

##### C. Family Impact

The General Counsel, as the Designated Official for Executive Order 12606, *The Family*, has determined that this NOFA, to the extent the funds provided under it are directed to families, has the potential for a beneficial impact on family formation, maintenance, and general well-being. Since any impact on families is beneficial, no further review is considered necessary.

##### D. Economic Opportunities for Low- and Very Low-Income Persons

All applicants are herein notified that the provisions of section 3 of the Housing and Urban Development Act of 1968, as amended, and the regulations in 24 CFR part 135 are applicable to funding awards made under this NOFA. One of the purposes of the assistance is to give to the greatest extent feasible, and consistent with existing Federal,

State, and local laws and regulations, job training, employment, contracting, and other economic opportunities to section 3 residents and section 3 business concerns. Tribes that receive HUD assistance described in this part shall comply with the procedures and requirements of this part to the maximum extent consistent with, but not in derogation of, compliance with section 7(b) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450e(b)).

*E. Section 102 of the HUD Reform Act: Documentation and Public Access Requirements; Applicant/Recipient Disclosures*

*Documentation and public access requirements.* HUD will ensure that documentation and other information regarding each application submitted pursuant to this NOFA are sufficient to indicate the basis upon which assistance was provided or denied. This material, including any letters of support, will be made available for public inspection for a five-year period beginning not less than 30 days after the award of the assistance. Material will be made available in accordance with the Freedom of Information Act (5 U.S.C. 552) and HUD's implementing regulations in 24 CFR part 15. In addition, HUD will include the recipients of assistance pursuant to this NOFA in its Federal Register notice of all recipients of HUD assistance awarded on a competitive basis. (See 24 CFR 12.14(a) and 12.16(b), and the notice published in the Federal Register on January 16, 1992 (57 FR 1942), for further information on these documentation and public access requirements.)

*Disclosures.* HUD will make available to the public for five years all applicant disclosure reports (HUD Form 2880) submitted in connection with this NOFA. Update reports (also Form 2880) will be made available along with the applicant disclosure reports, but in no case for a period less than three years. All reports—both applicant disclosures and updates—will be made available in accordance with the Freedom of Information Act (5 U.S.C. 552) and HUD's implementing regulations in 24 CFR part 15. (See 24 CFR part 12, subpart C, and the notice published in the Federal Register on January 16, 1992 (57 FR 1942), for further information on these disclosure requirements.)

*F. Section 103 of the HUD Reform Act*

HUD's regulation implementing section 103 of the Department of Housing and Urban Development

Reform Act of 1989 (42 U.S.C. 3537a), was published in the Federal Register on May 13, 1991 (56 FR 22088), and became effective on June 12, 1991. That regulation, codified as 24 CFR part 4, applies to this funding competition. The requirements of the rule continue to apply until the announcement of the selection of successful applicants.

HUD employees involved in the review of applications and in the making of funding decisions are restrained by part 4 from providing advance information to any person (other than an authorized employee of HUD) concerning funding decisions, or from otherwise giving any applicant an unfair competitive advantage. Persons who apply for assistance in this competition should confine their inquiries to the subject areas permitted under 24 CFR part 4. Applicants or employees who have ethics related questions should contact the HUD Office of Ethics at (202) 708-3815. (This is not a toll-free number.) For HUD employees who have specific program questions, such as whether a particular subject matter can be discussed with persons outside HUD, the employee should contact the appropriate Regional or Field Office Counsel, or Headquarters counsel for the program to which the question pertains.

*G. Prohibition Against Lobbying Activities*

The use of funds awarded under this NOFA is subject to the disclosure requirements and prohibitions of section 319 of the Department of Interior and Related Agencies Appropriations Act for Fiscal Year 1990 (31 U.S.C. 1352) (the Byrd Amendment), and the implementing regulations in 24 CFR part 87. These authorities prohibit recipients of Federal contracts, grants, or loans from using appropriated funds for lobbying the executive or legislative branches of the Federal government in connection with a specific contract, grant, or loan. The prohibition also covers the awarding of contracts, grants, cooperative agreements, or loans unless the recipient has made an acceptable certification regarding lobbying. Under 24 CFR part 87, applicants, recipients, and subrecipients of assistance exceeding \$100,000 must certify that no Federal funds have been or will be spent on lobbying activities in connection with the assistance. Indian Housing Authorities (IHAs) established by an Indian tribe as a result of the exercise of their sovereign power are excluded from coverage, but IHAs established under State law are not excluded from coverage.

I. The Catalog of Federal Domestic Assistance program number is 14.231.

Authority: 42 U.S.C. 11376; 42 U.S.C. 3535(d).

Dated: January 26, 1996.

Kevin Emanuel Marchman,  
*Acting Assistant Secretary for Public and Indian Housing.*

*Appendix 1—Statutory Amendments (Section I.B)*

National Affordable Housing Act Amendments: Sections (1)–(6) below describe the relevant NAHA amendments.

(1) *Extension of eligibility to Indian tribes.* Section 832(f) of NAHA (42 U.S.C. 11371–11378) expressly extends eligibility for assistance under the ESG program to Indian tribes, and has the effect of applying the same formula as used in the Community Development Block Grant (CDBG) program for determining the amount of ESG funds to be set aside for Indian tribes. The 1 percent figure for the Indian tribe set-aside is dictated by sections 832(f)(3) and 913(b) of NAHA (42 U.S.C. 5306).

(2) *Administrative costs.* Section 832(b)(1) of NAHA (42 U.S.C. 11378) permits recipients to use up to 5 percent of an ESG program grant for administrative purposes. This amount equals 5 percent of the total of amounts of ESG funds requested for all other eligible activities. Administrative costs include: costs of accounting for the use of grant funds, preparing reports for submission to HUD or to the State, obtaining program audits, conducting environmental reviews, coordinating program activities, and similar costs related to administering the grant. These costs do not include the costs of carrying out other activities eligible under the ESG program.

(3) *Use of funds for essential services.* Section 832(c) of NAHA (42 U.S.C. 11374(a)(2)(B)) increased the percentage of a grant that may be used to provide essential services from 20 percent to 30 percent. Consistent with this amendment, HUD will apply its waiver authority in section 414(b) of the McKinney Act to the new, higher 30 percent limitation. As with the previous 20 percent limit, the 30 percent limit is to be measured against the aggregate amount of each emergency shelter grant to an Indian tribe. Section 832(f)(6) of NAHA makes the limitations on the provision of essential services applicable to Indian tribes.

(4) *Use of funds for prevention of homelessness.* Homelessness prevention was added as a category of eligible activities by section 423 of the Stewart B. McKinney Homeless Assistance Amendments Act (Pub. L. 100-688, approved November 7, 1988), which also treated these activities as "essential services." However, section 832(d) of NAHA (42 U.S.C. 11374(a)(4)) withdraws homelessness prevention activities from categorization as "essential services," and imposes a separate limit of 30 percent of the aggregate amount of assistance to any recipient, including an Indian tribe, that may be used for efforts to prevent homelessness.

Thus, under NAHA, essential services and homelessness prevention are now each subject to a 30 percent cap. However, unlike



the category of essential services, there is no statutory authority to permit a waiver of the cap on the amount of assistance that may be used for homelessness prevention activities. By its express terms, the statutory waiver is available only in the category of essential services.

(5) *Confidentiality of records for family violence services.* Section 832(e) of NAHA (42 U.S.C. 11375(c)(5)) requires each recipient to certify that it will develop and implement procedures to ensure the confidentiality of records pertaining to any individual provided family violence prevention or treatment services with ESG program assistance. In addition, the address or location of any ESG-assisted housing used as a family violence shelter may not be made public without the written authorization of persons responsible for the operation of the shelter. This new certification is included in the application kit, as provided in Section III of this NOFA.

(6) *Establishes habitability standards.* Section 832(g) of NAHA (42 U.S.C. 11376(c)) requires the Secretary to prescribe the minimum standards of habitability appropriate to ensure that emergency shelters assisted by this program are environments that provide appropriate privacy, safety, and sanitary and other health-related conditions for homeless persons and families. A description of the Minimum Habitability Standards and the required certification is included in the application kit, as provided in Section III of this NOFA. The Habitability Standards that have been developed under section 832(g) of NAHA to apply to emergency shelters are as follows:

(a) *Structure and materials.* The shelter shall be structurally sound so as not to pose any threat to the health and safety of the occupants and so as to protect the occupants from the environment.

(b) *Access.* The shelter shall be accessible and capable of being utilized without unauthorized use of other private properties. The building shall provide an alternate means of egress in case of fire.

(c) *Space and security.* Each occupant shall be afforded adequate space and security for the occupant's person and belongings. Each occupant shall be provided an acceptable place to sleep.

(d) *Interior air quality.* Every room or space shall be provided with natural or mechanical ventilation. The shelter shall be free of pollutants in the air at levels that threaten the health of the occupants.

(e) *Water supply.* The water supply shall be free from contamination at levels that threaten the health of the recipients.

(f) *Sanitary facilities.* Shelter occupants shall have access to sanitary facilities that are in proper operating condition, can be used in privacy, and are adequate for personal cleanliness and the disposal of human waste.

(g) *Thermal environment.* The shelter shall have adequate heating and cooling facilities in proper operating condition.

(h) *Illumination and electricity.* The shelter shall have adequate natural or artificial illumination to permit normal indoor activities and to support the health and safety of occupants. Sufficient electrical sources shall be provided to permit use of essential electrical appliances while assuring safety from fire.

(i) *Food preparation and refuse disposal.* All food preparation areas shall contain suitable space and equipment to store, prepare, and serve food in a sanitary manner.

(j) *Sanitary condition.* The shelter and its equipment shall be maintained in sanitary condition.

*Housing and Community Development Act of 1992 Amendments:* Sections (7)–(9) below describe the relevant changes of the 1992 Act.

(7) *Certification of involvement of homeless individuals and families.* The recipient must certify that, to the maximum extent practicable, it will involve homeless individuals and families, through employment, volunteer services, or otherwise, in providing services and in constructing, renovating, maintaining, and operating facilities, when assistance is provided for those activities under the program.

(8) *Termination of assistance.* The recipient may terminate assistance provided to an individual or a family only in accordance with a formal process established by the recipient that recognizes the rights of the individuals affected, which may include a hearing.

(9) *Eligibility of staff costs.* Staff costs relating to the operation of emergency shelters are specifically recognized as an eligible activity, but not more than 10 percent of the amount of any grant may be used for these costs. Staff costs for maintenance of and security for emergency shelters will not be counted against the 10 percent cap.

#### APPENDIX 2.—HUD OFFICES OF NATIVE AMERICAN PROGRAMS

Tribes and IHAs located	ONAP address
East of the Mississippi River (including all of Minnesota and Iowa).	Eastern/Woodlands Office of Native American Programs, 5P, Metcalfe Federal Building, 77 West Jackson Boulevard, Chicago, Illinois 60604–3507, (312) 353–1282 or (800) 735–3239, TDD Numbers: 1–800–927–9275 or 312–886–3741.
Louisiana, Missouri, Kansas, Oklahoma, and Texas except for Isleta del Sur.	Southern Plains Office of Native American Programs, 6.IPI, 500 W. Main, Suite 400, Oklahoma City, Oklahoma 73102, (405) 553–7428, TDD Numbers: 405–231–4181 or 405–231–4891.
Colorado, Montana, Nebraska, North Dakota, South Dakota, Utah, and Wyoming.	Northern Plains Office of Native American Programs, 8P, First Interstate Tower North, 633 17th Street, Denver, Colorado 80202–3607, (303) 672–5462, TDD Number: 303–672–5248.
Arizona, California, New Mexico, Nevada, and Isleta del Sur in Texas.	Southwest Office of Native American Programs, 9EPID, Two Arizona Center, 400 North Fifth Street, Suite 1650, Phoenix, Arizona 85004–2361, (602) 379–4156, TDD Number: 602–379–4461.
	or
	Albuquerque Division of Native American Programs, 9EPIDI, Albuquerque Plaza, 201 3rd Street, N.W., Suite 1830, Albuquerque, New Mexico 87102–3368, (505) 766–1372, TDD Number: None.
	or
Idaho, Oregon, and Washington .....	Northern California Division of Native American Programs, 450 Golden Gate Avenue, 8th Floor, Box 36003, San Francisco, CA 94102–3448, (415) 436–8121, TDD Number: (415) 556–8357.
	Northwest Office of Native American Programs, 10PI, 909 First Avenue, Suite 300, Seattle, Washington 98104–1000, (206) 220–5270, TDD Number: (206) 220–5185.
Alaska .....	Alaska Office of Native American Programs, 10.1PI, 949 East 36th Avenue, Suite 401, Anchorage, Alaska 99508–4399, (907) 271–4633, TDD Number: (907) 271–4328.

#### Appendix 3—Checklist of Application Submission Requirements

Applicants must complete and submit applications in accordance with the instructions contained in the application kit. The following is a checklist of the

application contents that will be specified in the application kit:

- (1) Applicant Information, including name, address, contact person, and telephone number;
- (2) Standard Form 424;

—(3) Certifications of compliance with the requirements of:

- (a) 24 CFR 576.21(a)(4)(ii), concerning assistance provided for homelessness prevention activities; § 567.51(b)(2)(v), concerning the funding of ESG activities

- in commercial facilities; § 576.73, concerning the continued use of buildings as emergency shelters for the population to be served; § 576.75, concerning building standards; 576.77, concerning assistance to the homeless; and § 576.80, concerning displacement and relocation;
- (b) The Indian Civil Rights Act (25 U.S.C. 1301), and section 7(b) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450e(b));
  - (c) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794);
  - (d) The Age Discrimination Act of 1975 (42 U.S.C. 6101–07);
  - (e) Executive Orders 11625, 12432, and 12138, promoting the use of minority business enterprises and women-owned businesses to the maximum extent consistent with the Indian Self-Determination and Education Assistance Act;
  - (f) The requirements of 24 CFR part 24, concerning the Drug-Free Workplace Act of 1988;
  - (g) Section 832(e)(2)(C) of NAHA, concerning the confidentiality of records pertaining to any individual provided family violence prevention or treatment services;
  - (h) Section 832(g) of NAHA, concerning minimum habitability standards prescribed by the Department;
  - (i) Section 104(g) of the Housing and Community Development Act of 1974 and 24 CFR part 58, concerning assumption of the HUD environmental review responsibilities;
  - (j) Section 576.71(b)(2)(vii), concerning compliance with Tribal law in the submission of an application for an emergency shelter grant, and possession of legal authority to carry out emergency shelter grant activities;
  - (k) Prohibitions on the use of Federal funds for lobbying, and the completion of SF-LLL, Disclosure Form to Report Lobbying, if applicable;
  - (l) 42 U.S.C. 11375(c)(7), as added by the Housing and Community Development Act of 1992, concerning the involvement through employment, volunteer services, or otherwise, to the maximum extent practicable, of homeless individuals and families in constructing, renovating, maintaining, and operating facilities assisted under the ESG program, and in providing services for occupants of these facilities;
  - (m) Section 3 of the Housing and Urban Development Act of 1968, as amended, and the regulations in 24 CFR part 135;
  - (4) Form HUD-2880, Applicant/Recipient Disclosure/Update Form, if applicable;
  - (5) Project Summary and Proposed Budgets;
  - (6) Description of the homeless population to be served;
  - (7) Facility Description;
  - (8) Narrative addressing the rating criteria;
  - (9) Matching funds certification as required under § 576.51(b)(2)(ii), § 576.71, and section 415 of the McKinney Act (42 U.S.C. 11375(a)). Each grantee must match the funding provided by HUD with an equal amount of funds from sources other than under this part.
- These funds must be provided after the date of the grant award to the grantee.

[FR Doc. 96-5081 Filed 3-4-96; 8:45 am]

BILLING CODE 4210-33-P

Research in Education of Individuals  
With Disabilities Program

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Tuesday  
March 5, 1996

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**Part VII**

**Department of  
Education**

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**Research in Education of Individuals  
With Disabilities Program; Extension  
Notice**

**DEPARTMENT OF EDUCATION****[CFDA No.: 84.023C]****Office of Special Education and  
Rehabilitative Services; Research in  
Education of Individuals With  
Disabilities Program****ACTION:** Extension Notice.

**PURPOSE:** On August 10, 1995, the Secretary published in the Federal Register (60 FR 40956) a combined application notice (CAN) inviting applications for new awards for fiscal year 1996 under a number of the Department's direct grant and fellowship programs. Included in the CAN under the Research in Education of Individuals with Disabilities Program was a closing date for the Field-Initiated

Research Projects competition, CFDA No. 84.023C. On October 30, 1995 an extension notice was published in the Federal Register (60 FR 55247) that revised the closing date for that competition to March 29, 1996. The purpose of this notice is to revise, once again, the closing date for the Field-Initiated Research Projects competition.

**DEADLINE FOR TRANSMITTAL OF  
APPLICATIONS:** April 30, 1996.

This action is taken in consideration of the current proposals in the Congress that either eliminate or substantially reduce funding for the program. Extending the closing date for this competition allows the Department and potential applicants time to consider further developments related to the fiscal year 1996 appropriation.

**FOR FURTHER INFORMATION CONTACT:**

Claudette Carey, U.S. Department of Education, 600 Independence Avenue, S.W., room 3525, Switzer Building, Washington, D.C. 20202-2641. Telephone: (202) 205-9864. FAX: (202) 205-8105. Internet: Claudette\_\_\_\_@ed.gov.

Individuals who use a telecommunications device for the deaf (TDD) may call the TDD number: (202) 205-8953.

Program Authority: 20 U.S.C. 1441-1442, 34 CFR 324.

Dated: February 28, 1996.

Katherine D. Seelman,

*Acting Assistant Secretary for Special  
Education and Rehabilitative Services.*

[FR Doc. 96-5054 Filed 3-4-96; 8:45 am]

**BILLING CODE 4000-01-P**

Federal Register

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Tuesday  
March 5, 1996

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**Part VIII**

**Department of  
Education**

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**National Institute on Disability and  
Rehabilitation Research; Applications for  
New Awards Under the Research and  
Demonstration Program for Fiscal Years  
1996–1997; Notice**

**DEPARTMENT OF EDUCATION****[CFDA No.: 84.133A]****Office of Special Education and Rehabilitative Services; National Institute on Disability and Rehabilitation Research; Notice Inviting Applications for New Awards Under the Research and Demonstration Program for Fiscal Years 1996–1997**

*Purpose of Program:* Research and Demonstration Projects support research and demonstrations in single project areas on problems encountered by individuals with disabilities in their daily activities. These projects may conduct research on rehabilitation techniques and services, including analysis of medical, industrial, vocational, social, psychiatric, psychological, recreational, economic, and other factors to improve the rehabilitation of individuals with disabilities. In addition, the projects may conduct studies, analyses, and demonstrations of architectural and engineering design, including universal design, adapted to meet the special needs of individuals with disabilities.

*Eligible Applicants:* Parties eligible to apply for grants under this program are public and private nonprofit and for-profit agencies and organizations, including institutions of higher education and Indian tribes and tribal organizations.

*Deadline for Transmittal of Applications:* May 17, 1996.

*Application Available:* March 15, 1996.

*Available Funds:* \$425,000.

*Estimated Average Size of Awards Per Year:* Architectural and Engineering Design—\$250,000, Recreation—\$175,000.

*Estimated Number of Awards:* 2.

*Project Period:* 36 months.

*Applicable Regulations:* (a) The Education Department General Administrative Regulations (EDGAR), 34 CFR Parts 74, 75, 77, 80, 81, 82, 85, 86; and (b) the regulations for this program in 34 CFR Parts 350 and 351.

Note: The estimates of funding levels and awards in this notice do not bind the Department of Education to a specific level of funding or number of grants.

This notice supports the National Education Goal that calls for all Americans to possess the knowledge and skills necessary to compete in a global economy and exercise the rights and responsibilities of citizenship.

*Priorities:* Under 34 CFR 75.105(b)(2)(v) and (c)(3) and Section 204(a) of the Rehabilitation Act of 1973,

as amended, the Secretary gives an absolute preference to applications that meet one or both of the following priorities. The Secretary funds under this competition only applications that meet one or both of these absolute priorities:

**Absolute Priority 1—Architectural and Engineering Design**

Studies, analyses, and demonstrations utilizing architectural and engineering designs to address the special needs of individuals with disabilities.

*Invitational Priority 1:* Within absolute priority 1, the Secretary is particularly interested in applications that address the following invitational priority. However, under 34 CFR 75.105(c)(1) an application that meets an invitational priority does not receive competitive or absolute preference over other applications:

Universal design is a holistic approach to creating environments and products that are usable by many people regardless of their abilities or age (Strategies for Teaching Universal Design, ed. by P. Welch, Adaptive Environments Center, Boston, MA, 1995). Manufacturers who apply principles of universal design to their products are making a significant contribution toward promoting the independence and inclusion of persons with disabilities in the mainstream of society. They are also increasing the market for their products by making those products attractive to or useable by larger numbers of people.

Understanding the decision-making process of manufacturers who adopt principles of universal design can contribute to its increased utilization. The Secretary invites applications to investigate the factors contributing to the application of principles of universal design by manufacturers who have designed and marketed universally designed products.

**Absolute Priority 2—Recreation**

Studies and analysis on the effects of recreation on the rehabilitation of individuals with disabilities.

*Invitational Priority 2:* Within the absolute priority 2, the Secretary is particularly interested in applications that address the following invitational priority. However, under 34 CFR 75.105(c)(1) an application that meets an invitational priority does not receive competitive or absolute preference over other applications:

Regular physical exercise and the resulting fitness can reduce the likelihood of heart disease, obesity, low back pain, depression, and other ailments associated with inactivity.

Incorporating exercise into the lives of individuals with disabilities enables them to enjoy the physical and psychological benefits of fitness, achieve greater independence, and perform activities of daily living with less fatigue. The Secretary invites applications related to exercise and fitness for persons with disabilities. The Secretary invites applications on topics such as: (1) Measuring the fitness level of persons with disabilities and comparing it to the level of fitness of persons without disabilities; (2) evaluating the exercise habits of persons with disabilities; (3) determining the level of participation of persons with disabilities in utilizing fitness centers, programs, and products and identifying barriers to participation; or (4) designing modifications to exercise regimens to accommodate the needs of persons with disabilities.

**FOR APPLICATIONS CONTACT:** In order to obtain an application package, contact William H. Whalen, U.S. Department of Education, 600 Independence Avenue S.W., Switzer Building, Room 3411, Washington, D.C. 20202. Telephone: (202) 205-9141. Individuals who use a telecommunications device for the deaf (TDD) may call the TDD number at (202) 205-8887.

**FOR FURTHER INFORMATION CONTACT:** David Esquith, U.S. Department of Education, 600 Independence Avenue S.W., Switzer Building, Room 3424, Washington, D.C. 20202. Telephone: (202) 205-8801. Individuals who use a telecommunications device for the deaf (TDD) may call the TDD number at (202) 205-8133. Internet: DAVID\_\_\_ESQUITH@ED.GOV.

Information about the Department's funding opportunities, including copies of application notices for discretionary grant competitions, can be viewed on the Department's electronic bulletin board (ED Board), telephone (202) 260-9950; on the Internet Gopher Server at GOPHER.ED.GOV (under Announcements, Bulletins, and Press Releases); or on the World Wide Web at <http://www.ed.gov/money.html>.

However, the official application notice for a discretionary grant competition is the notice published in the Federal Register.

Program Authority: 29 U.S.C. 761a and 762.

Dated: February 28, 1996.

Katherine D. Seelman,  
Acting Assistant Secretary for Special Education and Rehabilitative Services.  
[FR Doc. 96-5055 Filed 3-4-96; 8:45 am]

BILLING CODE 4000-01-P

Antiflatulent Drug Products for Over-the-Counter Human Use

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Tuesday  
March 5, 1996

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**Part IX**

**Department of  
Health and Human  
Services**

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**Food and Drug Administration**

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**21 CFR Part 332**

**Antiflatulent Drug Products for Over-the-Counter Human Use; Final Rule**

**21 CFR PART 332****[DOCKET NO. 87N-0053]****RIN 0910-AA01****Antiflatulent Drug Products for Over-the-Counter Human use; Amendment of Monograph****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a final rule amending the monograph for over-the-counter (OTC) antiflatulent drug products by adding a statement of identity section to conform to the format of other OTC drug final monographs and by revising the indications to include additional descriptive terms, and by adding a definition for the term "antigas." FDA is issuing this final rule after considering public comments on the agency's proposed regulation and all new data and information on OTC antiflatulent drug products that have come to the agency's attention. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

**DATES:** Effective March 5, 1997; written comments by June 3, 1996.

**FOR FURTHER INFORMATION CONTACT:** William E. Gilbertson, Center for Drug Evaluation and Research (HFD-105), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2304.

**SUPPLEMENTARY INFORMATION:****I. Background**

In the Federal Register of June 4, 1974 (39 FR 19862), FDA issued a final monograph for OTC antiflatulent drug products (21 CFR part 332) that established conditions under which these drug products are generally recognized as safe and effective and not misbranded.

In the Federal Register of January 29, 1988 (53 FR 2716), the agency published a proposed amendment of the monograph for OTC antiflatulent drug products to add a statement of identity section to conform to the format of other OTC drug final monographs and to revise the indications for use to include additional descriptive terms describing the symptoms that are commonly referred to as "gas." The proposed statement of identity was "antiflatulent," "antigas," or "antiflatulent (antigas)." FDA issued that proposal after considering the report and recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products

(the Miscellaneous Internal Panel) and public comments on the advance notice of proposed rulemaking for OTC digestive aid drug products (47 FR 454, January 5, 1982), that was based on those recommendations. Interested persons were invited to submit comments, objections, or requests for oral hearing by March 29, 1988.

In the Federal Register of April 19, 1988 (53 FR 12778 and 12779), the agency extended the comment period from March 29, 1988, until May 27, 1988, to allow adequate time for one manufacturer to fully evaluate information it had received from the agency and to prepare comments to the notices of proposed rulemaking for OTC antiflatulent drug products and OTC digestive aid drug products.

In response to the proposed monograph amendment, three drug manufacturers and three physicians submitted comments. One comment requested an oral hearing before the Commissioner of Food and Drugs. That request concerned the inclusion of activated charcoal in the OTC antiflatulent monograph if the ingredient was found to be Category I in the OTC digestive aid monograph. The agency addressed the hearing request in comment 1 of the final rule for OTC digestive aid drug products (58 FR 54450 at 54451, October 21, 1993), and concluded that activated charcoal will not be included in either monograph, and a hearing is not necessary. Copies of the comments and the hearing request received are on public display in the Dockets Management Branch (H.A.-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23 Rockville, MD 20857, and may be seen between 9 a.m. and 4 p.m., Monday through Friday. Any additional information that has come to the agency's attention since publication of the proposed rule is also on public display in the Dockets Management Branch.

In proceeding with this final rule, the agency has considered all comments, objections, and the request for oral hearing. A summary of the comments and the new data with FDA's responses to them follows.

**II. Summary of the Comments Received**

1. One comment agreed with the agency's use of the term "antigas" as interchangeable with "antiflatulent." The comment expressed concern, however, that the agency was prohibiting other terminology, e.g., "antigas formulation relieves gas trapped in the intestine" or "for gas pain." The comment stated that the basis for the agency's labeling restriction appeared to be recommendations of the

Miscellaneous Internal Panel (47 FR 454), which were at variance with the findings of the Advisory Review Panel on OTC Antacid Drug Products (38 FR 8714, April 5, 1973) (the Antacid Panel) that recognized the cause of "bloating," "pressure," and "fullness" as being the result of gas. The comment cited the Antacid Panel's recommended indication "alleviate or relieve the symptoms of gas" for simethicone-containing products as support for its position that excess gas causes discomfort. The comment also cited the double-blind, placebo-controlled clinical study by McDonald, O'Leary, and Stratton (Ref. 1) as demonstrating that dosing with simethicone results in a reduction of gastrointestinal foam. Finally, the comment stated that terms such as "relieves gas trapped in the intestine," "for gas pain," and "relieves the symptoms of gas" should not be prohibited under the antiflatulent final monograph because consumers use these terms. The comment referred, specifically, to the consumer survey discussed in the proposed amendment (53 FR 2716) and indicated that the terms "bloating," "pressure," "stuffed feeling," and "fullness" are very meaningful to and used by consumers to describe "gas." The comment concluded by stating it is unclear whether the existing indication in § 332.30(a), "to alleviate or relieve the symptoms of gas," is still permitted because the proposal appears to omit this indication.

The agency is no longer including the indication "to alleviate or relieve the symptoms of gas" in the antiflatulent monograph. As explained in the proposal to amend the antiflatulent monograph (53 FR 2716), the agency modified the wording of this indication to ("alleviates" or "relieves") "the symptoms referred to as gas." The agency also recognized that consumers use the terms "bloating, pressure, fullness,"

"or" "stuffed feeling" "to refer to gas and provided an additional indication statement that includes these terms: ("alleviates" or "relieves") ("bloating, pressure, fullness, or stuffed feeling) commonly referred to as gas."

The agency disagrees with the comment's statement that the Antacid Panel recognized the cause of "bloating," "pressure," and "fullness" as being the result of gas. The Antacid Panel stated that claims or indications such as "full feeling" or "gas" encourage the user to draw conclusions as to the cause of such symptoms, "a conclusion that even the medical profession is incapable of drawing at this time," and placed claims such as "full feeling" or "gas" in Category III (38



FR 8714 at 8722 to 8723). Further, while these symptoms describe discomfort, as noted by the Antacid Panel, the Panel did not include "pain" as one of the symptoms of gas (38 FR 8722 to 8723).

In the proposal to amend the antifatulent monograph, the agency also stated that phrases such as "antigas formulation relieves gas trapped in the intestine" and "for gas pain" would be considered inappropriate (53 FR 2716). The agency reviewed the study by McDonald, O'Leary, and Stratton (Ref. 1), cited by the comment, which discusses the effectiveness of simethicone in eliminating foam and bubbles that may obscure the visual field in peroral endoscopy. According to the study results, simethicone is effective as a defoaming agent, but the study does not define the term "bubbles" or explain the source of the foam or bubbles that obscure the visual field. Without knowing whether the bubbles are derived from gas or air, the study cannot support the phrases "relieves gas trapped in the intestine" and "for gas pain."

In the advance notice of proposed rulemaking for OTC digestive aid drug products (47 FR 454), the Miscellaneous Internal Panel discussed at length the question of whether excessive gas is the causative agent of distress in the upper gastrointestinal tract and concluded that data were insufficient to make this assumption. In the tentative final monograph for OTC digestive aid drug products (53 FR 2706, January 29, 1988), the agency acknowledged that the word "gas" is commonly used by consumers. Therefore, the agency had no objection to use of the word "gas" in the labeling of OTC digestive aid drug products, provided there was no implication that the presence of gas, in the literal sense of excess gas bubbles in the gastrointestinal tract, is the cause of the symptoms. The agency discussed the consumer survey mentioned by the comment and agreed that a number of terms were commonly used by consumers in describing what is commonly, if not accurately, referred to as "gas" (53 FR 2706 at 2710). However, the terms did not include "gas pain."

Based on all of the data evaluated to date, the agency finds the claims "antigas formulation relieves gas trapped in the intestine" and "for gas pain" inappropriate for OTC antifatulent drug products. The agency concludes that the general term "antigas" is appropriate when used for the indications provided in the monograph, e.g., "relieves the symptoms referred to as gas." However, the agency acknowledges that the term could be interpreted by some as the

mechanism of action for these products. While this is not supported scientifically, the agency concludes that this term is understood by consumers and is an appropriate statement of identity for these products.

The agency is adding the following definition for the term "antigas" in the monograph: "Antigas is a term that may be used interchangeably with the term antifatulent. Neither term should be considered as describing the mechanism of action of the active ingredient contained in the product." This definition appears in new § 332.3 of the final monograph.

#### Reference

(1) McDonald, G. B., R. O'Leary, and C. Stratton, "Pre-Endoscopic Use of Oral Simethicone," *Gastrointestinal Endoscopy*, 24:283, 1978.

2. Three comments, submitting to both the OTC antifatulent and digestive aid drug products rulemakings, contended that activated charcoal was solely an antifatulent drug and did not belong in the digestive aid drug products rulemaking. Another comment expressed concern that activated charcoal was not included as a monograph ingredient in the 1988 proposal to amend the final monograph for OTC antifatulent drug products. The comments cited studies (Refs. 1 through 5) in the literature to support monograph status for activated charcoal. One comment mentioned that physicians who use charcoal to treat lower intestinal gas symptoms indicate that charcoal is effective under certain circumstances. The comment referred to studies by Jain et al. (not cited), as well as its own studies (not submitted), as evidence that activated charcoal decreased intestinal gas and relieved associated symptoms. The comment argued that the need for additional studies and ongoing research should not deter the availability or use of activated charcoal for excessive gas and related symptoms for which it is reasonably expected to be effective. The comment felt charcoal was not approved because it had a stigma as "an old remedy," which is difficult to overcome.

Two advisory review panels (Antacid (38 FR 8714) and Miscellaneous Internal (47 FR 454)) evaluated charcoal for antifatulent and digestive aid use. Both panels concluded that more data were needed to establish effectiveness for these uses.

Subsequently, after the comments were submitted, the agency received additional data, including studies done by one comment and by Jain et al. (referenced by the comment). The agency discussed these studies and the

references provided by the comments in the final rule for OTC digestive aid drug products (58 FR 54450 at 54451). The agency found the data insufficient to support the effectiveness of activated charcoal as a digestive aid or as an antifatulent (58 FR 54453). No new data have been provided to the agency.

The agency has never attached a "stigma" to a drug because it has been in the marketplace for many years. The agency has proposed a number of very old ingredients (e.g., aspirin, bran, cascara, and psyllium) as monograph ingredients. The data that have been provided have not been adequate to include activated charcoal in a monograph for use as an antifatulent. Manufacturers have the option to petition the agency to amend the antifatulent monograph in the future should additional data become available to support the effectiveness of activated charcoal as an antifatulent.

#### References

(1) Jain, N. K. et al., "Efficacy of Activated Charcoal in Reducing Intestinal Gas: A Double-Blind Clinical Trial," *American Journal of Gastroenterology*, 81:532-535, 1986.

(2) Jain, N. K., V. P. Patel, and C. Pitchumoni, "Activated Charcoal, Simethicone, and Intestinal Gas: A Double-Blind Study," *Annals of Internal Medicine*, 105:61-62, 1986.

(3) Potter, T., C. Ellis, and M. Levitt, "Activated Charcoal: In Vivo and In Vitro Studies of Effect on Gas Formation," *Gastroenterology*, 88:620-624, 1985.

(4) Hall, R. G., H. Thompson, and A. Strother, "Effects of Orally Administered Activated Charcoal on Intestinal Gas," *The American College of Gastroenterology*, 75:192-196, 1981.

(5) Vargo, D., L. Ozick, and M. H. Floch, "The Effect of Activated Charcoal on Dietary Carbohydrate Fermentation" *American Journal of Gastroenterology*, (abst.), 82:950, 1987.

3. Three manufacturers submitted protocols to study the effectiveness of activated charcoal in decreasing gastrointestinal distress. One manufacturer did not pursue studies after 1989.

The agency met with representatives of the other two manufacturers (Ref. 1) to discuss their study protocols. Both manufacturers submitted revised protocols in response to the agency's comments. The agency provided written comments on only one of the protocols (Ref. 2) because one manufacturer indicated that it intended to begin its study and that no further review by the agency was necessary.

Subsequently, one manufacturer informed FDA that it had decided not to pursue studies (Ref. 3). The other manufacturer (Ref. 4) has not submitted

any study results to date. In the absence of new data, the agency concludes there is no basis to include activated charcoal in the OTC antifatulent drug products monograph at this time. Manufacturers have the option to petition the agency to amend the antifatulent monograph in the future should additional data become available to support the effectiveness of activated charcoal as an antifatulent.

#### References

(1) Memorandum of Meeting between FDA representatives and representatives from Kramer Laboratories and Requa, Inc., coded MM4, Docket No. 81N-0106, Dockets Management Branch.

(2) Letter from W. E. Gilbertson, FDA, to J. Geils, Requa, Inc., dated July 22, 1994, coded LET 20, Docket No. 81N-0106, Dockets Management Branch.

(3) Memorandum of Telephone Conversation between M. Barach, of Akin, Gump, Strauss, Hauer & Feld on behalf of Kramer Laboratories, and B. Ryland, FDA, coded MT3, Docket No. 81N-0106, Dockets Management Branch.

(4) Memorandum of Telephone Conversation between B. Marlin, Requa Consultant, and B. Ryland, FDA, coded MT4, Docket No. 81N-0106, Dockets Management Branch.

#### III. The Agency's Final Conclusions

The agency has carefully evaluated the comments' proposals and concludes that the terms "antigas" and "antifatulent" are interchangeable. The agency is providing manufacturers the option of using either term or both as the statement of identity for their products. Although "antigas" is now the preferable term, the agency is also allowing "antifatulent."

In respect to the one comment's concern that activated charcoal is not a monograph ingredient, the agency points out that manufacturers of products containing this ingredient have had over 20 years to provide sufficient data to support claims for activated charcoal as an antifatulent and have failed to do so. Accordingly, simethicone remains the only antifatulent monograph ingredient.

Interested persons may, on or before June 3, 1996, submit to the Dockets Management Branch (address above) written comments on these warnings. Comments should be identified with the docket number found in brackets in the heading of this document. Three copies of all comments are to be submitted, except that individuals may submit one copy. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

#### IV. Analysis of Impacts

No comments regarding the economic impact of this rulemaking were received. FDA has examined the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory action as defined by the Executive Order and, thus, is not subject to review under the Executive Order. This final rule provides for minor labeling revisions that can be implemented at very little cost by manufacturers at the next printing of labels. The agency is providing 12 months for these revisions to be made and, thus, believes that this rule will have no significant economic impact. Accordingly, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

#### V. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Rather, the labeling statements are a "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

#### VI. Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### List of Subjects in 21 CFR Part 332

Labeling, Over-the-counter drugs. Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 332 is amended as follows:

#### PART 332—ANTIFLATULENT PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 332 is revised to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. New § 332.3 is added to Subpart A to read as follows:

#### Subpart A—General Provisions

##### § 332.3 Definitions.

As used in this part:

**Antigas.** A term that may be used interchangeably with the term antifatulent. Neither term should be considered as describing the mechanism of action of the active ingredient contained in the product.

3. Subpart D consisting of §§ 332.30 and 332.31 is redesignated as Subpart C; and § 332.30 is amended by revising the section heading; by redesignating paragraphs (a), (b), and (c) as paragraphs (b), (c), and (d), respectively; by adding new paragraph (a); and by revising newly redesignated paragraph (b) to read as follows:

#### Subpart—Labeling

##### § 332.30 Labeling of antifatulent drug products.

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as an "antifatulent,"

"antigas," or "antifatulent (antigas)."

(b) Indications. The labeling of the product states, under the heading "Indications," one or more of the phrases listed in this paragraph (b), as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) (Select one of the following: "Alleviates or Relieves") "the symptoms referred to as gas."

(2) (Select one of the following: "Alleviates" or "Relieves") (select one or more of the following: "bloating," "pressure," "fullness," or "stuffed feeling") "commonly referred to as gas."

\* \* \* \* \*

Dated: February 23, 1996.

William K. Hubbard,

*Associate Commissioner for Policy  
Coordination.*

[FR Doc. 96-5118 Filed 3-4-96; 8:45 am]

**BILLING CODE 4160-01-F**

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Tuesday  
March 5, 1996

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**Part X**

**The President**

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**Proclamation 6867—Declaration of a  
National Emergency and Invocation of  
Emergency Authority Relating to the  
Regulation of the Anchorage and  
Movement of Vessels**



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# Presidential Documents

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Title 3—

Proclamation 6867 of March 1, 1996

The President

## Declaration of a National Emergency and Invocation of Emergency Authority Relating to the Regulation of the Anchorage and Movement of Vessels

By the President of the United States of America

### A Proclamation

WHEREAS, on February 24, 1996, Cuban military aircraft intercepted and destroyed two unarmed U.S.-registered civilian aircraft in international airspace north of Cuba;

WHEREAS the Government of Cuba has demonstrated a ready and reckless willingness to use excessive force, including deadly force, in the ostensible enforcement of its sovereignty;

WHEREAS, on July 13, 1995, persons in U.S.-registered vessels who entered into Cuban territorial waters suffered injury as a result of the reckless use of force against them by the Cuban military; and

WHEREAS the entry of U.S.-registered vessels into Cuban territorial waters could again result in injury to, or loss of life of, persons engaged in that conduct, due to the potential use of excessive force, including deadly force, against them by the Cuban military, and could threaten a disturbance in international relations;

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by the authority vested in me by the Constitution and the laws of the United States of America, including section 1 of title II of Public Law 65-24, ch. 30, June 15, 1917, as amended (50 U.S.C. 191), sections 201 and 301 of the National Emergencies Act (50 U.S.C. 1601 *et seq.*), and section 301 of title 3, United States Code, find and do hereby proclaim that a national emergency does exist by reason of a disturbance or threatened disturbance of international relations. In order to address this national emergency and to secure the observance of the rights and obligations of the United States, I hereby authorize and direct the Secretary of Transportation (the "Secretary") to make and issue such rules and regulations as the Secretary may find appropriate to regulate the anchorage and movement of vessels, and delegate to the Secretary my authority to approve such rules and regulations, as authorized by the Act of June 15, 1917.

Section 1. The Secretary may make rules and regulations governing the anchorage and movement of any vessel, foreign or domestic, in the territorial waters of the United States, which may be used, or is susceptible of being used, for voyage into Cuban territorial waters and that may create unsafe conditions and threaten a disturbance of international relations. Any rule or regulation issued pursuant to this proclamation may be effective immediately upon issuance as such rule or regulation shall involve a foreign affairs function of the United States.

Sec. 2. The Secretary is authorized to inspect any vessel, foreign or domestic, in the territorial waters of the United States, at any time; to place guards on any such vessel; and, with my consent expressly hereby granted, take full possession and control of any such vessel and remove the officers and crew, and all other persons not specifically authorized by the Secretary to go or remain on board the vessel when necessary to secure the rights and obligations of the United States.

Sec. 3. The Secretary may request assistance from such departments, agencies, officers, or instrumentalities of the United States as the Secretary deems necessary to carry out the purposes of this proclamation. Such departments, agencies, officers, or instrumentalities shall, consistent with other provisions of law and to the extent practicable, provide requested assistance.

Sec. 4. The Secretary may seek assistance from State and local authorities in carrying out the purposes of this proclamation. Because State and local assistance may be essential for an effective response to this emergency, I urge all State and local officials to cooperate with Federal authorities and to take all actions within their lawful authority necessary to prevent the unauthorized departure of vessels intending to enter Cuban territorial waters.

Sec. 5. All powers and authorities delegated by this proclamation to the Secretary may be delegated by the Secretary to other officers and agents of the United States Government unless otherwise prohibited by law.

Sec. 6. This proclamation shall be immediately transmitted to the Congress and published in the Federal Register.

IN WITNESS WHEREOF, I have hereunto set my hand this first day of March, in the year of our Lord nineteen hundred and ninety-six, and of the Independence of the United States of America the two hundred and twentieth.



Executive Order

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Tuesday  
March 5, 1996

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## Part XI

# The President

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Proclamation 6868—Irish-American  
Heritage Month, 1996

Proclamation 6869—Save Your Vision  
Week, 1996





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# Presidential Documents

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Title 3—

Proclamation 6868 of March 1, 1996

The President

Irish-American Heritage Month, 1996

By the President of the United States of America

## A Proclamation

I am pleased to count myself among the over 40 million Americans who can trace their heritage back to Ireland. Like so many of our forebears, immigrants from the Emerald Isle came to this country seeking dignity and prosperity, and they brought with them traditions rooted in the values of family and faith. Some arrived on our shores even before our Nation was founded, lending their energy to the establishment of our Republic; nine sons of Ireland signed the Declaration of Independence, and our first President, George Washington, proudly claimed Irish ancestry.

The largest wave of Irish immigration occurred 150 years ago, when more than 1 million people left Ireland for America as potato blight and famine devastated their homeland. These sons and daughters of Erin transformed our cities, stimulating industry and commerce from New York to Boston to Chicago. In pursuing the American Dream, they set an example of courage, hard work, and determination that was to be followed again and again by hopeful newcomers.

Today, Irish Americans celebrate this history and the contributions that their brethren have made to all aspects of American life—providing leadership in Government, the law, business, finance, literature, and the arts. Renewed interest in Gaelic culture has led to university courses in Irish studies, and hundreds of Saint Patrick's Day parades across the country attest to the vigor of Irish American communities. This month and throughout the year, let us recognize the gifts brought to America by children of Ireland and honor the strengths they have added to our national character.

In tribute to all Irish Americans, the Congress, by Public Law 103-379, has designated March 1996 as "Irish-American Heritage Month" and has authorized and requested the President to issue a proclamation in observance of this month.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim March 1996 as Irish-American Heritage Month. I call upon all the people of the United States to observe this month with appropriate ceremonies, activities, and programs.

IN WITNESS WHEREOF, I have hereunto set my hand this first day of March, in the year of our Lord nineteen hundred and ninety-six, and of the Independence of the United States of America the two hundred and twentieth.



## Presidential Documents

Proclamation 6869 of March 1, 1996

### Save Your Vision Week, 1996

By the President of the United States of America

#### A Proclamation

Vision is a remarkable gift. Our eyes allow us to read, to see the faces of our loved ones, and to experience many of life's greatest pleasures. Too often, we take our sight for granted and must be reminded that our eyes require regular care and attention. The more we learn about preventing eye disease and vision loss, the better equipped we will be to take care of these vital organs.

Many young people suffer from vision-related learning disabilities that jeopardize their academic success. However, with early intervention, such sight problems are often easily correctable. Senior citizens, too, are particularly vulnerable to eye difficulties, but we are fortunate that advances in medical research are improving our understanding of the diseases that often rob older Americans of their sight.

As a result of these new technologies and discoveries in the field of eye care, many diseases that would have caused permanent sight loss just decades ago can now be treated with excellent prospects for full recovery. For example, people with diabetes can reduce their risk of blindness with timely laser surgery, the effects of glaucoma can often be prevented, and studies are exploring the role of vitamins and minerals in slowing the progression of age-related macular degeneration and cataract.

To educate people about these strides and to encourage all Americans to protect their precious eyesight, the Congress, by joint resolution approved December 30, 1963 (77 Stat. 629; 36 U.S.C. 169a), has authorized and requested the President to proclaim the first week in March of each year as "Save Your Vision Week."

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, do hereby proclaim March 3 through March 9, 1996, as Save Your Vision Week. I urge all the people of the United States to participate in this observance by making eye care and eye safety a priority and to recognize the important contributions that vision research makes to our lives. I invite eye care professionals, the media, and all public and private organizations committed to the goal of sight preservation to join in activities that educate our citizens about the simple steps they can take to save their vision.

IN WITNESS WHEREOF, I have hereunto set my hand this first day of March, in the year of our Lord nineteen hundred and ninety-six, and of the Independence of the United States of America the two hundred and twentieth.



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The rules and proposed rules in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

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